

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

Printing date 26.09.2019

Revision: 27.09.2018

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

· **Product identifier**

· **Trade name:** Opalescence™ Boost 40% Activator Gel

· **Article number:** 71087

· **Index number:** SDS 196-001.08

· **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 Westhoyer 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

2 Hazards identification

· **Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008**



GHS03 flame over circle

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



GHS05 corrosion

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



GHS07

Acute Tox. 4 H302 Harmful if swallowed.

Acute Tox. 4 H332 Harmful if inhaled.

· **Label elements**

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

The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by

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Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.

· **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 label before use.

P221 Take any precaution to avoid mixing with combustibles.

P303+P361+P353 IF ON SKIN (or hair): 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.

· **Additional information:**

EUH031 Contact with acids liberates toxic gas.

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterisation: Mixtures**

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

· **Dangerous components:**

CAS: 56-81-5 EINECS: 200-289-5	Glycerine substance with a Community workplace exposure limit	<80%
CAS: 7757-79-1 EINECS: 231-818-8	Potassium Nitrate ⚠ Ox. Sol. 2, H272; ⚠ Skin Irrit. 2, H315; STOT SE 3, H335-H336	<30%
CAS: 1310-58-3 EINECS: 215-181-3	Potassium Hydroxide ⚠ Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H302	<30%
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	<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.

- **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 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.

- **Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

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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:**
Protect from heat.
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.
Protect from heat and direct sunlight.
- **Specific end use(s)** Professional Dental Tooth Whitening Activator

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

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

56-81-5 Glycerine

WEL (Great Britain) Long-term value: 10 mg/m³

1310-58-3 Potassium Hydroxide

WEL (Great Britain) Short-term value: 2 mg/m³

· **Additional information:** The lists valid during the making 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 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.

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· **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

· **Information on basic 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 (solid, gas):** Not applicable.· **Decomposition temperature:** Not determined.· **Auto-ignition temperature:** Product is not selfigniting.· **Explosive properties:** Product does not present an explosion hazard.· **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

· **Vapour pressure:** Not determined.· **Density at 20 °C:** 1.37 g/cm³

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· 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.
· Solvent content:	
Organic solvents:	<70 %
VOC (EC)	0.00 %
· Solids content:	<50.0 %
· Other information	No further relevant information available.

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:** Contact with acids releases toxic gases.
- **Conditions to avoid:**
 - Heat
 - Moisture
- **Incompatible materials:**
 - Organic materials
 - Metals
 - Acids
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity**
 - Harmful if swallowed or if inhaled.

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

ATE (Acute Toxicity Estimates)

Oral	LD50	407 mg/kg
Dermal	LD50	2,059 mg/kg (rat)
Inhalative	LC50/4 h	>0.243 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)

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Dermal	LC50 Fish	>5,000 mg/l (Fish)
	LD50	>21,900 mg/kg (rat)
Inhalative		10,000 mg/kg (rabbit)
	LC50/4 h	>0.1425 mg/l (rat)
7757-79-1 Potassium Nitrate		
Oral	LD50	3,015 mg/kg (rat)
		1,901 mg/kg (rabbit)
Dermal	LC50 Fish	1,378 mg/l (Fish)
	LD50	>5,000 mg/kg (rat)
	LC50(Daphnia magna)	490 mg/l (daphnia)
1310-58-3 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)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**
Causes severe skin burns and eye damage.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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 Glycerine

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

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.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

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· **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.

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**

HP2	Oxidising
HP5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
HP6	Acute Toxicity
HP8	Corrosive
HP12	Release of an acute toxic gas

· **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**

· **ADR, IMDG, IATA**

UNI760

· **UN proper shipping name**

· **ADR**

1760 CORROSIVE LIQUID, N.O.S. (POTASSIUM HYDROXIDE Mixture)

· **IMDG, IATA**

CORROSIVE LIQUID, N.O.S. (POTASSIUM HYDROXIDE Mixture)

· **Transport hazard class(es)**

· **ADR, IMDG, IATA**



· **Class**

8 Corrosive substances.

· **Label**

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· Packing group · ADR, IMDG, IATA	II
· Environmental hazards:	Not applicable.
· Special precautions for user · Danger code (Kemler): · EMS Number: · Stowage Category · Stowage Code	Warning: Corrosive substances. 80 F-A,S-B B SW2 Clear of living quarters.
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category · Tunnel restriction code	2 E
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1760 CORROSIVE LIQUID, N.O.S. (POTASSIUM HYDROXIDE Mixture), 8, II

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **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**
- **REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3**
- **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**
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.

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*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.*· **Department issuing SDS:** Regulatory Affairs· **Contact:** Customer Service· **Abbreviations and acronyms:***ADR: Accord européen sur le transport 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)**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**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*