

## Safety data sheet according to UK REACH

Printing date 25.03.2025

Version number 1

Revision: 25.03.2025

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

- **Product identifier**
- **Trade name:** *Opalescence™ Office Activator*
- **Article number:** *SDS 349-001.05R01, 71195*
- **Relevant identified uses of the substance or mixture and uses advised against**  
*Professional Dental Bleaching Gel, Part 2 of 2*
- **Application of the substance / the mixture** *Professional Dental Bleaching Gel, Part 2 of 2*
- **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  
Office Phone: +49(0)2203-35-92-0*
- **Further information obtainable from:** *Customer Service*
- **Emergency telephone number:**  
*During normal opening times: +1 (801) 553-4862  
CHEMTREC (NORTH AMERICA) : +1 (800) 424-9300  
(INTERNATIONAL) : +(703) 527-3887*

### 2 Hazards identification

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



*Skin Irrit. 2 H315 Causes skin irritation.  
Eye Irrit. 2 H319 Causes serious eye irritation.*

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** *Void*
- **Hazard pictograms** *GHS07*
- **Signal word** *Warning*
- **Hazard statements**  
*H315 Causes skin irritation.  
H319 Causes serious eye irritation.*
- **Precautionary statements**  
*P264 Wash thoroughly after handling.  
P280 Wear protective gloves / eye protection / face protection.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*

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P332+P313 *If skin irritation occurs: Get medical advice/attention.*  
 P362+P364 *Take off contaminated clothing and wash it before reuse.*  
 P337+P313 *If eye irritation persists: Get medical advice/attention.*

### 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	<95%
CAS: 7757-79-1 EINECS: 231-818-8	Potassium Nitrate ⚠ Ox. Sol. 2, H272; ⚠ Skin Irrit. 2, H315; STOT SE 3, H335-H336	<4%
CAS: 1310-73-2 EINECS: 215-185-5	Sodium Hydroxide ⚠ Skin Corr. 1A, H314	<3%

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

### 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 not possible.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** If symptoms persist consult 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 spray  
Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters:**
- **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** 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).

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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:** See product labeling.
- **Information about fire - and explosion protection:** No special measures required.
- **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:** Not required.
- **Further information about storage conditions:**  
See product labelling.  
Keep container tightly sealed.
- **Specific end use(s)** Professional Dental Bleaching Gel, Part 2 of 2

### 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/m<sup>3</sup>

**1310-73-2 Sodium Hydroxide**

WEL Short-term value: 2 mg/m<sup>3</sup>

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

- **Exposure controls**

- **Appropriate engineering controls** No further data; see section 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:** Not required.

- **Hand protection**



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.

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- **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**

· <b>Physical state</b>	Fluid
· <b>Colour:</b>	Dark red
· <b>Odour:</b>	Odourless
· <b>Odour threshold:</b>	Not determined.
· <b>Melting point/freezing point:</b>	Undetermined.
· <b>Boiling point or initial boiling point and boiling range</b>	Undetermined.
· <b>Flammability</b>	Not applicable.
· <b>Lower and upper explosion limit</b>	
· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.
· <b>Flash point:</b>	Not applicable.
· <b>Decomposition temperature:</b>	Not determined.
· <b>pH at 20 °C</b>	>12
· <b>Viscosity:</b>	
· <b>Kinematic viscosity</b>	Not determined.
· <b>Dynamic:</b>	Not determined.
· <b>Solubility</b>	
· <b>water:</b>	Partly soluble.
· <b>Partition coefficient n-octanol/water (log value)</b>	Not determined.
· <b>Vapour pressure:</b>	Not determined.
· <b>Density and/or relative density</b>	
· <b>Density at 20 °C:</b>	1.3 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.

- **Other information**

- **Appearance:**

- **Form:** Gel

- **Important information on protection of health and environment, and on safety.**

- **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

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· 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	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

### 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:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **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** Based on available data, the classification criteria are not met.

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

##### 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)

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### 1310-73-2 Sodium Hydroxide

Oral	LD50	130-340 mg/kg (rat)
	LC50 Fish	160 mg/l (Fish)
Dermal	LD50	1,350 mg/kg (rabbit)
	Absolute lethal concentration	180 ppm (Fish)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **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)

### 1310-73-2 Sodium Hydroxide

EC50 40.38 mg/kg (Water Flea)

- **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.
- **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.*  
*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.*

## 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.*

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### 14 Transport information

· UN number or ID number · ADR, IMDG, IATA	UNI760
· UN proper shipping name · ADR · IMDG, IATA	1760 CORROSIVE LIQUID, N.O.S. (Sodium Hydroxide) CORROSIVE LIQUID, N.O.S. (Sodium Hydroxide)
· Transport hazard class(es) · ADR, IMDG, IATA	
	
· Class · Label	8 Corrosive substances. 8
· Packing group · ADR, IMDG, IATA	III
· Environmental hazards:	Not applicable.
· Special precautions for user · EMS Number:	Warning: Corrosive substances. F-A,S-B
· Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ)	5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· UN "Model Regulation":	UN 1760 CORROSIVE LIQUID, N.O.S. (SODIUM HYDROXIDE), 8, III

### 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.	
· Poisons Act	
· Regulated explosives precursors	
None of the ingredients is listed.	
· Regulated poisons	
None of the ingredients is listed.	
· Reportable explosives precursors	
7757-79-1	Potassium Nitrate
	Listed

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· **Reportable poisons**

1310-73-2	Sodium Hydroxide	12% of total caustic alkalinity
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· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **Chemical safety assessment:**

The product meets the toxicological profile required for cosmetics per the EU cosmetic regulation, Regulation (EC) No. 1223/2009.

### 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.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H335 May cause respiratory irritation.

H336 May cause drowsiness or dizziness.

· **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

ATE: Acute toxicity estimate values

Ox. Sol. 2: Oxidizing solids – 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

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· **\* Data compared to the previous version altered.**