

## 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 Gel
- **Article number:** SDS 350-001.09R01, 71194
- **Relevant identified uses of the substance or mixture and uses advised against**  
Professional Dental Tooth Bleaching Gel, Part 1 of 2
- **Application of the substance / the mixture** Professional Dental Tooth Bleaching Gel, Part 1 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:**  
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**



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**  
H319 Causes serious eye irritation.
  - **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.  |
| P264           | Wash thoroughly after handling.  |
| P280           | Wear 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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P337+P313

If eye irritation persists: Get medical advice/attention.

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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	<55%
CAS: 7722-84-1 EINECS: 231-765-0	Hydrogen Peroxide ⚠ Ox. Liq. 1, H271; ⚠ Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H332 Specific concentration limits: Ox. Liq. 1; H271: $C \geq 70\%$ Ox. Liq. 2; H272: $50\% \leq C < 70\%$ Skin Corr. 1A; H314: $C \geq 70\%$ Skin Corr. 1B; H314: $50\% \leq C < 70\%$ Skin Irrit. 2; H315: $35\% \leq C < 50\%$ Eye Dam. 1; H318: $C \geq 8\%$ Eye Irrit. 2; H319: $5\% \leq C < 8\%$ STOT SE 3; H335: $C \geq 35\%$	<8%
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	≤0.3%

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

### 4 First aid measures

- **Description of first aid measures**
- **After inhalation:** This product is a viscous gel, therefore chance of inhalation is not possible.
- **After skin contact:** Generally the product does not irritate the skin.
- **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:** 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.

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- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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 Tooth Bleaching Gel, Part 1 of 2

## 8 Exposure controls/personal protection

- **Control parameters**

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

<b>56-81-5 Glycerin</b>	
<b>WEL</b>	Long-term value: 10 mg/m <sup>3</sup>
<b>7722-84-1 Hydrogen Peroxide</b>	
<b>WEL</b>	Short-term value: 2.8 mg/m <sup>3</sup> , 2 ppm Long-term value: 1.4 mg/m <sup>3</sup> , 1 ppm

- **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.  
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

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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/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>	White
· <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>	4.8-6.8
· <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>	1.2 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.**

· <b>Ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	Not determined.

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· <b>Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	Void
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	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:

##### ATE (Acute Toxicity Estimates)

Oral	LD50	5,570 mg/kg
Dermal	LD50	60,764 mg/kg (rat)
Inhalative	LC50/4 h	177 mg/l

##### 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)
Dermal	LC50 Fish	>5,000 mg/l (Fish)
	LD50	>21,900 mg/kg (rat) 10,000 mg/kg (rabbit)

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**7722-84-1 Hydrogen Peroxide**

Oral	LC50 Fish	16.4 mg/l (Fish)
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**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:**
- **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)
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**7722-84-1 Hydrogen Peroxide**

EC50	1.38 mg/l (Algae)
	2.4 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.
- **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.

**13 Disposal considerations**· **Waste treatment methods**· **Recommendation**

Dispose of contents/container in accordance with international, federal, state, and local regulations.

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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

· <b>UN number or ID number</b> · <b>ADR, ADN, IMDG, IATA</b>	not regulated
· <b>UN proper shipping name</b> · <b>ADR, ADN, IMDG, IATA</b>	not regulated
· <b>Transport hazard class(es)</b> · <b>ADR, ADN, IMDG, IATA</b> · <b>Class</b>	not regulated
· <b>Packing group</b> · <b>ADR, IMDG, IATA</b>	not regulated
· <b>Environmental hazards:</b>	Not applicable.
· <b>Special precautions for user</b>	Not Applicable
· <b>Maritime transport in bulk according to IMO instruments</b>	Not applicable.
· <b>UN "Model Regulation":</b>	not regulated

### 15 Regulatory information

· <b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b>		
· <b>NIOSH-Ca (National Institute for Occupational Safety and Health)</b>		
None of the ingredients is listed.		
· <b>Poisons Act</b>		
· <b>Regulated explosives precursors</b>		
7722-84-1	Hydrogen Peroxide	12%
· <b>Regulated poisons</b>		
None of the ingredients is listed.		
· <b>Reportable explosives precursors</b>		
None of the ingredients is listed.		
· <b>Reportable poisons</b>		
7681-49-4	Sodium Fluoride	Listed
1310-73-2	Sodium Hydroxide	12% of total caustic alkalinity
· <b>Directive 2012/18/EU</b>		
· <b>Named dangerous substances - ANNEX I</b> None of the ingredients is listed.		
· <b>Chemical safety assessment:</b>		
The product meets the toxicological profile required for cosmetics per the EU cosmetic regulation, Regulation (EC) No. 1223/2009.		

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## 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**

H271 May cause fire or explosion; strong oxidiser.

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.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

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

ATE: Acute toxicity estimate values

Ox. Liq. 1: Oxidizing liquids – Category 1

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

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