

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

Printing date 10.10.2022

Version number 1

Revision: 10.10.2022

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

- **Product identifier**
- **Trade name:** *Opalescence™ Office-Mixed*
- **Article number:** SDS 351-001.05, 71195, 71194
- **Relevant identified uses of the substance or mixture and uses advised against** *Professional Dental Bleaching Gel*
- **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*
- 
- 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**  
*The product is not classified, according to the GB CLP regulation.*
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** *Void*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*

**3 Composition/information on ingredients**

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

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· <b>Dangerous components:</b>		
CAS: 56-81-5 EINECS: 200-289-5	Glycerin substance with a Community workplace exposure limit	>50-<70%
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; $C \geq 35\%$	6%%

· **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.
- **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.
- **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.

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- **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.
- **Specific end use(s)** Professional Dental Bleaching Gel

### 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>
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**7722-84-1 Hydrogen Peroxide**

WEL	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 item 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.

- **Hand protection**

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** Goggles recommended during refilling

- **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>  | Red-brown       |
| · <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. |

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· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable.
· Decomposition temperature:	Not determined.
· pH at 20 °C	6.8-8.2
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Partly soluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C:	1.2-1.3 g/cm <sup>3</sup>
· Relative density	Not determined.
· Vapour density	Not determined.

· Other information	
· Appearance:	
· Form:	Gel
· 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	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.

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- **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**

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

#### ATE (Acute Toxicity Estimates)

Oral	LD50	8,171-9,098 mg/kg
Dermal	LD50	69,832 mg/kg (rat)
Inhalative	LC50/4 h	407 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)

#### 7722-84-1 Hydrogen Peroxide

Oral	LC50 Fish	16.4 mg/l (Fish)
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- **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)

- **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.

### 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.

### 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

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

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**· Relevant phrases from Section 3***H271 May cause fire or explosion; strong oxidiser.**H302 Harmful if swallowed.**H314 Causes severe skin burns and eye damage.**H332 Harmful if inhaled.***· 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**Ox. Liq. 1: Oxidizing liquids – Category 1**Acute Tox. 4: Acute toxicity – Category 4**Skin Corr. 1A: Skin corrosion/irritation – Category 1A***· \* Data compared to the previous version altered.**

GB