

## Safety Data Sheet according to WHS Regulations

Printing date 16.04.2024

Revision: 16.04.2024

### 1 Identification

- **Product identifier**
- **Trade name:** Opal™ by Opalescence™ Whitening Mouthwash
- **Article number:** SDS 485-001.01R01, 1011892, 5447
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **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
- Ultradent Australia Pty Ltd.  
Level 22/2 Market Street  
Sydney NSW 2000  
Australia  
Email: info.anz@ultradent.com  
Toll Free: 1-800-290929
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**  
CHEMTREC (NORTH AMERICA) : (800) 424-9300  
(INTERNATIONAL) : +(703) 527-3887

### 2 Hazard(s) Identification

- **Classification of the substance or mixture**  
The product is not classified, according to the Globally Harmonised System (GHS).
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void

### 3 Composition and Information on Ingredients

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

· <b>Dangerous components:</b>		
57-55-6	Propylene Glycol	>0.1-<5%
7722-84-1	Hydrogen Peroxide	>1.35-<1.65%
	⚠ Ox. Liq. 1, H271; ⚠ Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H332	
56-81-5	Glycerin	≤1%
	⚠ Serious eye damage/irritation – Category 2A, H319	

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

### 4 First Aid Measures

- **General information:** *No special measures required.*
- **After inhalation:** *Supply fresh air; consult doctor in case of complaints.*
- **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.*
- **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 Fire Fighting Measures

- **Suitable extinguishing agents:** *Use fire extinguishing methods suitable to surrounding conditions.*
- **Special hazards arising from the substance or mixture** *No further relevant information available.*
- **Protective equipment:** *No special measures required.*

### 6 Accidental Release Measures

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

- **Handling:**
- **Precautions for safe handling:**  
*See product labeling.*  
*No special measures required.*
- **Information about fire - and explosion protection:** *No special measures required.*
- **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:** *None.*
- **Specific end use(s)** *No further relevant information available.*

### 8 Exposure controls and personal protection

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

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<b>Ingredients with limit values that require monitoring at the workplace:</b>	
<b>57-55-6 Propylene Glycol</b>	
WES	Long-term value: 474* 10** mg/m <sup>3</sup> , 150* ppm *vapour&particulates; **particulates only
<b>7722-84-1 Hydrogen Peroxide</b>	
WES	Long-term value: 1.4 mg/m <sup>3</sup> , 1 ppm
<b>56-81-5 Glycerin</b>	
TWA	Short-term value: 10 mg/m <sup>3</sup>
WES	Long-term value: 10 mg/m <sup>3</sup> inhalable dust

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

· **Personal protective equipment:**

· **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

· **Respiratory protection:** Not required.

· **Protection of hands:**

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:** Goggles recommended during refilling

· **Body protection:** Protective work clothing

## 9 Physical and Chemical Properties

· **General Information**

· **Appearance:**

· **Form:** Liquid

· **Colour:** Colourless

· **Odour:** Mint

· **Odour threshold:** Not determined.

· **pH-value at 20 °C:** 2.3-4.3

· **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.

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· <b>Vapour pressure:</b>	Not determined.
· <b>Density at 20 °C:</b>	1.0186 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with</b>	
· <b>water:</b>	Fully miscible.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
· <b>Dynamic:</b>	Not determined.
· <b>Kinematic:</b>	Not determined.
· <b>Other information</b>	No further relevant information available.

### 10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **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 toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

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

##### ATE (Acute Toxicity Estimates)

Oral	LD50	33,333 mg/kg
Inhalative	LC50/4 h	733 mg/l

##### 57-55-6 Propylene Glycol

Oral	LD50	18,000 mg/kg (rabbit)
	LC50 Fish	>5,000 mg/l (Fish)
Dermal	LD50	20,800 mg/kg (rabbit)

##### 7722-84-1 Hydrogen Peroxide

Oral	LC50 Fish	16.4 mg/l (Fish)
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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)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.

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- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **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:

##### 57-55-6 Propylene Glycol

EC50 18,100 mg/kg (Algae)

##### 7722-84-1 Hydrogen Peroxide

EC50 1.38 mg/l (Algae)

2.4 mg/l (daphnia)

##### 56-81-5 Glycerin

EC50 &gt;10,000 mg/kg (Bacteria)

- **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.
- **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.
- **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

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

#### · ADG, IMDG, IATA

not regulated

### · UN proper shipping name

#### · ADG, IMDG, IATA

not regulated

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· <b>Transport hazard class(es)</b>	
· <b>ADG, ADN, IMDG, IATA</b>	
· <b>Class</b>	not regulated
· <b>Packing group</b>	
· <b>ADG, IMDG, IATA</b>	not regulated
· <b>Environmental hazards:</b>	Not applicable.
· <b>Special precautions for user</b>	Not Applicable
· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</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**

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **Australian Inventory of Industrial Chemicals**

7732-18-5 Water

57-55-6 Propylene Glycol

7722-84-1 Hydrogen Peroxide

50-70-4 Sorbitol

56-81-5 Glycerin

87-99-0 Xylitol

6155-57-3 Sodium Saccharine Powder

Citric Acid, Anhydrous

· **Standard for the Uniform Scheduling of Medicines and Poisons**

7722-84-1 Hydrogen Peroxide

S5, S6, S10

· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **Directive 2012/18/EU**

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

· **Chemical safety assessment:** A chemical safety assessment has not been carried out.

### 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 oxidizer.

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

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· **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

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. 1: Oxidizing liquids – Category 1

Acute Tox. 4: Acute toxicity – Category 4

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A

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

AU