

Safety Data Sheet
acc. to OSHA HCS

Printing date 03/27/2024

Reviewed on 03/27/2024

1 Identification

- **Product identifier**
- **Trade name:** Opal™ by Opalescence™ Whitening Mouthwash
- **Article number:** SDS 485-001.01R01, 1011892, 5447
- **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
- **Information department:** 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 Harmonized System (GHS).
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

3 Composition/information on ingredients

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

· **Dangerous components:**

57-55-6	Propylene Glycol	>0.1-<5%
7722-84-1	Hydrogen Peroxide	>1.35-<1.65%

(Contd. on page 2)

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/27/2024

Reviewed on 03/27/2024

Trade name: Opal™ by Opalescence™ Whitening Mouthwash

56-81-5 Glycerin

(Contd. of page 1)

≤1%

4 First-aid measures

- **Description of 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

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **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

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

US

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/27/2024

Reviewed on 03/27/2024

Trade name: Opal™ by Opalescence™ Whitening Mouthwash

(Contd. of page 2)

8 Exposure controls/personal protection

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

· **Control parameters**

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

57-55-6 Propylene Glycol

WEEL Long-term value: 10 mg/m³

7722-84-1 Hydrogen Peroxide

PEL Long-term value: 1.4 mg/m³, 1 ppm

REL Long-term value: 1.4 mg/m³, 1 ppm

TLV Long-term value: 1 ppm
A3

56-81-5 Glycerin

PEL Long-term value: 15* 5** mg/m³
mist; *total dust **respirable fraction

TLV TLV withdrawn-insufficient data human occup. exp.

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

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

The usual precautionary measures for handling chemicals should be followed.

· **Breathing equipment:** 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 is based 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

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Liquid

Color: Colorless

· **Odor:** Mint

· **Odor threshold:** Not determined.

(Contd. on page 4)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/27/2024

Reviewed on 03/27/2024

Trade name: **Opal™ by Opalescence™ Whitening Mouthwash**

(Contd. of page 3)

· pH-value at 20 °C:	2.3-4.3
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined
· Flash point:	Not applicable
· Flammability (solid, gaseous):	Not applicable.
· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density at 20 °C:	1.0186 g/cm ³
· Relative density	Not determined
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Soluble
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined
· Other information	No further relevant information available.

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 toxicological effects**
- **Acute toxicity:**

· LD/LC50 values that are relevant for classification:		
ATE (Acute Toxicity Estimate)		
Oral	LD50	33,333 mg/kg
Inhalative	LC50/4 h	733 mg/l

(Contd. on page 5)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/27/2024

Reviewed on 03/27/2024

Trade name: Opal™ by Opalescence™ Whitening Mouthwash

(Contd. of page 4)

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)
------	-----------	------------------

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)

· **Primary irritant effect:**

· **on the skin:** No irritant effect.

· **on the eye:** No irritating effect.

· **Sensitization:** No sensitizing effects known.

· **Additional toxicological information:**

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

7722-84-1	Hydrogen Peroxide	3
-----------	-------------------	---

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

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	>10,000 mg/kg (Bacteria)
------	--------------------------

· **Persistence and degradability** No further relevant information available.

· **Behavior in environmental systems:**

· **Bioaccumulative potential** No further relevant information available.

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/27/2024

Reviewed on 03/27/2024

Trade name: Opal™ by Opalescence™ Whitening Mouthwash

(Contd. of page 5)

- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
*Water hazard class 1 (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 packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

<ul style="list-style-type: none"> · UN-Number · DOT, IMDG, IATA 	Not Regulated
<ul style="list-style-type: none"> · UN proper shipping name · DOT, IMDG, IATA 	Not Regulated
<ul style="list-style-type: none"> · Transport hazard class(es) · DOT, ADN, IMDG, IATA · Class 	Not Regulated
<ul style="list-style-type: none"> · Packing group · DOT, IMDG, IATA 	Not Regulated
<ul style="list-style-type: none"> · Environmental hazards: 	Not Applicable.
<ul style="list-style-type: none"> · Special precautions for user 	Not Applicable
<ul style="list-style-type: none"> · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code 	Not Applicable.
<ul style="list-style-type: none"> · UN "Model Regulation": 	Not Regulated

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **Sara**

<ul style="list-style-type: none"> · Section 355 (extremely hazardous substances): 	7722-84-1 Hydrogen Peroxide
<ul style="list-style-type: none"> · Section 313 (Specific toxic chemical listings): 	None of the ingredients is listed.

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/27/2024

Reviewed on 03/27/2024

Trade name: Opal™ by Opalescence™ Whitening Mouthwash

(Contd. of page 6)

· **TSCA (Toxic Substances Control Act):**

57-55-6	Propylene Glycol	ACTIVE
7722-84-1	Hydrogen Peroxide	ACTIVE
56-81-5	Glycerin	ACTIVE

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)**

7722-84-1	Hydrogen Peroxide	A3
-----------	-------------------	----

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

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.

· **Department issuing SDS:** Environmental, Health, and Safety

· **Contact:** Customer Service

· **Date of preparation / last revision** 03/27/2024

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

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

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

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