Safety Data Sheet
acc. to OSHA HCS

Printing date 11/03/2023 Reviewed on 11/01/2023

1 Identification

· **Product identifier**

· **Trade name: Opal™ by Opalescence™ 10% - Opal™ by Opalescence™ 15% - Opal™ by Opalescence™ 20%**

· **Article number:** SDS 503-001.01R01. 1007923, 5770 - 1007926, 5771 - 1007929, 5772.
· **Application of the substance / the mixture** Professional Dental Teeth Whitening 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

· **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**

GHS07

Acute Toxicity - Inhalation 4	H332 Harmful if inhaled.
Skin Irritation 2	H315 Causes skin irritation.
Eye Irritation 2A	H319 Causes serious eye irritation.
Sensitization - Skin 1	H317 May cause an allergic skin reaction.

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** GHS07
· **Signal word** Warning

· **Health Hazard-determining components of labeling:**
Carbamide Peroxide
Sodium Hydroxide
Oils, Peppermint
· **Hazard statements**
H332 Harmful if inhaled.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
· **Precautionary statements**

P261	Avoid breathing dust/fume/gas/mist/vapors/spray
P264	Wash thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated work clothing must not be allowed out of the workplace.
P280	Wear protective gloves / eye protection / face protection.

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Printing date 11/03/2023 Reviewed on 11/01/2023

Trade name: Opal™ by Opalescence™ 10% - Opal™ by Opalescence™ 15% - Opal™ by Opalescence™ 20%

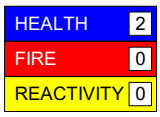
(Contd. of page 1)

P302+P352 If on skin: Wash with plenty of water.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312 Call a poison center/doctor if you feel unwell.
P362+P364 Take off contaminated clothing and wash it before reuse.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P363 Wash contaminated clothing before reuse.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**
· **NFPA ratings (scale 0 - 4)**

Health = 2
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 2
Fire = 0
Reactivity = 0

3 Composition/information on ingredients

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

· **Dangerous components:**

56-81-5	Glycerin	>20-<40%
124-43-6	Carbamide Peroxide	>10-<30%
9003-01-4	Polyacrylic Acid	>1-<10%
25322-68-3	Polyethylene Glycol	>1-<10%
1310-73-2	Sodium Hydroxide	>0.1-<5%
8006-90-4	Oils, Peppermint	<1%

4 First-aid measures

· **Description of first aid measures**
· **General information:**
Immediately remove any clothing soiled by the product.
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
· **After inhalation:**
This product is a viscous gel, therefore chance of inhalation is extremely low.
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:**
If skin irritation continues, consult a doctor.
Immediately wash with water and soap and rinse thoroughly.

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Trade name: Opal™ by Opalescence™ 10% - Opal™ by Opalescence™ 15% - Opal™ by Opalescence™ 20%

(Contd. of page 2)

· **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing:** If swallowed in large quantities seek medical attention.
· **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:**
Water spray
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:**
Wear fully protective suit.
Mouth respiratory protective device.

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).
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
· **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**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
· **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:**
See product labelling.
Keep receptacle tightly sealed.

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Trade name: Opal™ by Opalescence™ 10% - Opal™ by Opalescence™ 15% - Opal™ by Opalescence™ 20%

(Contd. of page 3)

· **Specific end use(s)** Professional Dental Teeth Whitening Gel

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:**
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

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.
9003-01-4 Polyacrylic Acid	
TWA	Short-term value: 0.05 mg/m³
25322-68-3 Polyethylene Glycol	
WEEL	Long-term value: 10 mg/m³ (H); MW>200
1310-73-2 Sodium Hydroxide	
PEL	Long-term value: 2 mg/m³
REL	Ceiling limit value: 2 mg/m³
TLV	Ceiling limit value: 2 mg/m³

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

· **Exposure controls**
· **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.
· **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
· **Protection of hands:**

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 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.

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Printing date 11/03/2023 Reviewed on 11/01/2023

Trade name: Opal™ by Opalescence™ 10% - Opal™ by Opalescence™ 15% - Opal™ by Opalescence™ 20%

(Contd. of page 4)

· **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:**

Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Gel
Color:	Colorless
· **Odor:**	Mint
· **Odor threshold:**	Not determined.
· **pH-value:**	Not determined.
· **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 at 20 °C:**	23.3 hPa
· **Density at 20 °C:**	1.2-1.3 g/cm³
· **Relative density**	Not determined
· **Vapor density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
Water:	Partly soluble
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
Dynamic:	Not determined.
Kinematic:	Not determined

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Printing date 11/03/2023 Reviewed on 11/01/2023

Trade name: Opal™ by Opalescence™ 10% - Opal™ by Opalescence™ 15% - Opal™ by Opalescence™ 20%

(Contd. of page 5)

· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity** Stable
· **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** Excess heat
· **Incompatible materials:**
Strong Alkalis
Metals
· **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	4,483-11,724 mg/kg
Dermal	LD50	46,552 mg/kg (rabbit)

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)
124-43-6 Carbamide Peroxide		
Oral	LD50	>2,000 mg/kg (rat)
9003-01-4 Polyacrylic Acid		
Oral	LC50 Fish	580 mg/l (Fish)
25322-68-3 Polyethylene Glycol		
Oral	LD50	19,600 mg/kg (Guinea pig)
		17,300 mg/kg (mouse)
		>10,000 mg/kg (rat)
	LC50 Fish	>100 mg/l (Fish)
Dermal	LD50	>20,000 mg/kg (rabbit)
	LC50(Daphnia magna)	>10,000 mg/l (Water Flea) (Toxicity to aquatic invertebrates)
1310-73-2 Sodium Hydroxide		
Oral	LD50	130-340 mg/kg (rat)

(Contd. on page 7)

Safety Data Sheet
acc. to OSHA HCS

Trade name: Opal™ by Opalescence™ 10% - Opal™ by Opalescence™ 15% - Opal™ by Opalescence™ 20%

(Contd. of page 6)

	LC50 Fish	160 mg/l (Fish)
Dermal	LD50	1,350 mg/kg (rabbit)
	Absolute lethal concentration	180 ppm (Fish)
8006-90-4 Oils, Peppermint		
Oral	LD50	2,490 mg/kg (mouse)
		2,426 mg/kg (rat)

· **Primary irritant effect:**
· **on the skin:** Irritant to skin and mucous membranes.
· **on the eye:** Irritating effect.
· **Sensitization:** Sensitization possible through skin contact.
· **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Harmful
Irritant

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**		
9003-01-4	Polyacrylic Acid	3

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Germ cell mutagenicity** Does not meet the classification criteria for this hazard class.
· **Carcinogenicity** Polyacrylic Acic is listed as a Group 3 IARC carcinogen.
· **Reproductive toxicity** Does not meet the classification criteria for this hazard class.
· **Specific target organ toxicity - single exposure** Does not meet the classification criteria for this hazard class.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**	
56-81-5 Glycerin	
EC50	>10,000 mg/kg (Bacteria)
9003-01-4 Polyacrylic Acid	
EC50	174 mg/kg (daphnia)
1310-73-2 Sodium Hydroxide	
EC50	40.38 mg/kg (Water Flea)

· **Persistence and degradability** No further relevant information available.
· **Behavior 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 2 (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.

(Contd. on page 8)

Safety Data Sheet
acc. to OSHA HCS

Printing date 11/03/2023 Reviewed on 11/01/2023

Trade name: Opal™ by Opalescence™ 10% - Opal™ by Opalescence™ 15% - Opal™ by Opalescence™ 20%

(Contd. of page 7)

· **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.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

· **UN-Number**	
· **DOT, IMDG, IATA**	Not Regulated
· **UN proper shipping name**	
· **DOT, IMDG, IATA**	Not Regulated
· **Transport hazard class(es)**	
· **DOT, ADN, IMDG, IATA**	
· **Class**	Not Regulated
· **Packing group**	
· **DOT, IMDG, IATA**	Not Regulated
· **Environmental hazards:**	Not Applicable.
· **Special precautions for user**	Not Applicable
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not Applicable.
· **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**

· **Section 355 (extremely hazardous substances):**
None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**
None of the ingredients is listed.

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

56-81-5	Glycerin	ACTIVE
124-43-6	Carbamide Peroxide	ACTIVE
9003-01-4	Polyacrylic Acid	ACTIVE
25322-68-3	Polyethylene Glycol	ACTIVE

(Contd. on page 9)

Safety Data Sheet
acc. to OSHA HCS

Trade name: Opal™ by Opalescence™ 10% - Opal™ by Opalescence™ 15% - Opal™ by Opalescence™ 20%

(Contd. of page 8)

1310-73-2	Sodium Hydroxide	ACTIVE
8006-90-4	Oils, Peppermint	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)**

None of the ingredients is listed.

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

None of the ingredients is listed.

· **Chemical safety assessment:**
The 10-16% products meet 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.

· **Department issuing SDS:** Environmental, Health, and Safety
· **Contact:** Customer Service
· **Date of preparation / last revision** 11/03/2023
· **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
Acute Toxicity - Inhalation 4: Acute toxicity – Category 4
Skin Irritation 2: Skin corrosion/irritation – Category 2
Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A

(Contd. on page 10)

Safety Data Sheet
acc. to OSHA HCS

Trade name: Opal™ by Opalescence™ 10% - Opal™ by Opalescence™ 15% - Opal™ by Opalescence™ 20%

(Contd. of page 9)

Sensitization - Skin 1: Skin sensitisation – Category 1

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