



Safety Data Sheet

acc. to OSHA HCS

Printing date 07/16/2025

Reviewed on 07/16/2025

1 Identification

- **Product identifier**
- **Trade name:** Opalescence™ Fluoride Free Whitening Toothpaste
- **Article number:** SDS 514-001.01R01, 1012614, 5759
- **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
(800) 552-5512
- **Information department:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : +1 (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS08 Health hazard

Germ Cell Mutagenicity 2 H341 Suspected of causing genetic defects.
Carcinogenicity 1B H350 May cause cancer.



GHS07

Eye Irritation 2A H319 Causes serious eye irritation.
Sensitization - Skin 1 H317 May cause an allergic skin reaction.

- **Label elements**
- **GHS label elements** The product is classified according to the Globally Harmonized System (GHS)
- **Hazard pictograms** GHS07, GHS08
- **Signal word** Danger
- **Health Hazard-determining components of labeling:**
Natural Mint - 106205
- **Hazard statements**
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H341 Suspected of causing genetic defects.
H350 May cause cancer.
- **Precautionary statements**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing dust/fume/gas/mist/vapors/spray
P264 Wash thoroughly after handling.

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- P272 Contaminated work clothing must not be allowed out of the workplace.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P302+P352 If on skin: Wash with plenty of water.
 P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P308+P313 IF exposed or concerned: Get medical advice/attention.
 P321 Specific treatment (see on this label).
 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.
 P405 Store locked up.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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

3 Composition/information on ingredients

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

56-81-5	Glycerin	≥10-<40%
112926-00-8	Synthetic Amorphous Silica	>10-≤25%
	Plantapon ACG 35 (Disodium Cocoyl Glutamate)	≥1-<10%
	Trade Secret	≥1-<5%
	Natural Mint - 106205	≥1-<5%

· **Additional information:**

The specific chemical identity of composition is being withheld as a trade secret. The specific chemical identity is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of paragraph §1910.1200.

4 First-aid measures

· **Description of first aid measures**· **After inhalation:**

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:** Immediately wash with water and soap and rinse thoroughly.· **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.

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- **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:**
Dispose contaminated material as waste according to section 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**
See product labeling.
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
- **Information about protection against explosions and fires:** Keep respiratory protective device available.
- **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:** Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 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.

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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.

112926-00-8 Synthetic Amorphous Silica

PEL 20mppcf or 80mg/m³ /%SiO₂

REL Long-term value: 6 mg/m³
See Pocket Guide App. C

TLV TLV withdrawn

Trade Secret

TWA Short-term value: 0.8 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.

Store protective clothing separately.

Avoid contact with the eyes.

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.

· **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

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9 Physical and chemical properties

· Information on basic physical and chemical properties	
· General Information	
· Appearance:	
Form:	Paste
Color:	White to Off-White
· Odor:	Mint
· Odor threshold:	Not determined.
· pH-value at 20 °C:	6.5-8.5
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined
· Flash point:	Not applicable
· Flammability:	Not determined.
· Decomposition temperature:	Not determined.
· Ignition temperature:	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 applicable.
· Density at 20 °C:	1.3 g/cm ³
· Relative density	Not determined
· Vapor density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with	
Water:	Soluble
· Partition coefficient (n-octanol/water): Not determined.	
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· 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.

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11 Toxicological information

· **Information on toxicological effects**· **Acute toxicity:**· **LD/LC50 values that are relevant for classification:****ATE (Acute Toxicity Estimate)**

Oral	LD50	29,070 mg/kg
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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)

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

Inhalative	LC50/4 h	>0.1425 mg/l (rat)
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112926-00-8 Synthetic Amorphous Silica

Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)
Inhalative	LC50/4 h	>0.69 mg/l (rat)

Trade Secret

Oral	LD50	>15,000 mg/kg (mouse)
		>3,300 mg/kg (rat)
	LC50 Fish	>10,000 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>5,000 mg/kg (rabbit)
Inhalative	LC50/4 h	0.139 mg/l (rat)

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

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

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

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

None of the ingredients is listed.

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12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

56-81-5 Glycerin

EC50 >10,000 mg/kg (Bacteria)

Trade Secret

EC50 >1,000 mg/kg (daphnia)

- **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 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.

- **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**

MARPOL 73/78 and the IBC Code

Not Applicable.

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· UN "Model Regulation": Not Regulated

15 Regulatory information

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

· 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.

· National regulations:

· Information about limitation of use:

Workers are not allowed to be exposed to the hazardous carcinogenic materials contained in this preparation.
Exceptions can be made by the authorities in certain cases.

- 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 07/16/2025 / -

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· 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**Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A**Sensitization - Skin 1: Skin sensitisation – Category 1**Germ Cell Mutagenicity 2: Germ cell mutagenicity – Category 2**Carcinogenicity 1B: Carcinogenicity – Category 1B***· * Data compared to the previous version altered.**

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