

Safety Data Sheet

according to WHS Regulations

Printing date 02.01.2024

Revision: 02.01.2024

1 Identification

- **Product identifier**
- **Trade name:** *Opal™ by Opalescence™ Original Toothpaste*
- **Article number:** SDS 502-001.01R01, 1008310, 5760
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Toothpaste
- **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**



Serious eye damage/irritation – Category 2A H319 Causes serious eye irritation.

Skin Sens. 1

H317 May cause an allergic skin reaction.

- **Label elements**
- **GHS label elements** The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
methyl salicylate
- **Hazard statements**
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.
P103 Read label before use.

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P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P280 Wear protective gloves / eye protection / face protection.
 P305+P351+P338 **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P337+P313 If eye irritation persists: Get medical advice/attention.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

3 Composition and Information on Ingredients

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

· **Dangerous components:**

56-81-5	Glycerin ⚠ Serious eye damage/irritation – Category 2A, H319	>20-<40%
112926-00-8	Synthetic Amorphous Silica	>10-<30%
119-36-8	methyl salicylate ⚠ Repr. 2, H361d; ⚠ Acute Tox. 4, H302; Skin Sens. 1B, H317	>0.1-<5%
151-21-3	Sodium Lauryl Sulfate ⚠ Acute Tox. 3, H311; ⚠ Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335	>0.1-<5%
8006-90-4	Oils, Peppermint ⚠ Asp. Tox. 1, H304; ⚠ Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; Skin Sens. 1, H317; Flam. Liq. 4, H227	<1%
7681-49-4	Sodium Fluoride ⚠ Acute Tox. 3, H301; Acute Tox. 2, H310; ⚠ Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319	<1%
1310-73-2	Sodium Hydroxide ⚠ Acute Tox. 3, H301; ⚠ Skin Corr. 1A, H314; Eye Dam. 1, H318; ⚠ Acute Tox. 4, H312	<1%

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

4 First Aid Measures

- **General information:** Immediately remove any clothing soiled by the product.
- **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.
- **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.

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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:** 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:**
See product labeling.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **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:** Keep container tightly sealed.
- **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.

Ingredients with limit values that require monitoring at the workplace:

56-81-5 Glycerin

TWA Short-term value: 10 mg/m³WES Long-term value: 10 mg/m³
inhalable dust

112926-00-8 Synthetic Amorphous Silica

WES Long-term value: 10 mg/m³

1310-73-2 Sodium Hydroxide

WES Peak limitation: 2 mg/m³

- **Additional information:** The lists valid during the making were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.

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Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes.

Avoid contact with the eyes and skin.

· **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· **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 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

9 Physical and Chemical Properties

· **General Information**

· **Appearance:**

· **Form:**

Fluid

· **Colour:**

According to product specification

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **pH-value at 20 °C:**

6.3-7.6

· **Change in condition**

· **Melting point/freezing point:**

Undetermined.

· **Initial boiling point and boiling range:**

Undetermined.

· **Flash point:**

177 °C

· **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.

· **Vapour pressure:**

Not determined.

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· Density at 20 °C:	1.214 g/cm ³
· Relative density	Not determined.
· Vapour 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.
· Other information	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	33,249 mg/kg
Dermal	LD50	23,077 mg/kg

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)

112926-00-8 Synthetic Amorphous Silica

Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)

119-36-8 methyl salicylate

Oral	LD50	890 mg/kg (ATE) 887 mg/kg (rat) 2,800 mg/kg (rabbit)
	LC50 Fish	19.8 mg/l (Fish)

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Dermal	LD50	>5,000 mg/kg (rabbit)
151-21-3 Sodium Lauryl Sulfate		
Oral	LD50	1,288 mg/kg (rat)
	LC50 Fish	14.67-15.51 mg/l (Fish)
	LC50(Daphnia magna) (static)	1.8 mg/l (daphnia)
8006-90-4 Oils, Peppermint		
Oral	LD50	2,490 mg/kg (mouse)
		2,426 mg/kg (rat)
7681-49-4 Sodium Fluoride		
Oral	LD50	52 mg/kg (mouse)
	LC50 Fish (static)	17 mg/l (Fish)
Dermal	LD50	175 mg/kg (rat)
1310-73-2 Sodium Hydroxide		
Oral	LD50	130-340 mg/kg (rat)
	LC50 Fish	160 mg/l (Fish)
Dermal	LD50	1,350 mg/kg (rabbit)
	Absolute lethal concentration	180 ppm (Fish)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **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:	
56-81-5 Glycerin	
EC50	>10,000 mg/kg (Bacteria)
119-36-8 methyl salicylate	
EC50	28 mg/kg (daphnia)
Aqua toxicity	1.6 mg/l (Algae)
151-21-3 Sodium Lauryl Sulfate	
EC50 (static)	16.5 mg/kg (Crustacean)
	50.6-52.3 mg/kg (daphnia)
7681-49-4 Sodium Fluoride	
EC50	272 mg/kg (Algae)
	98 mg/kg (daphnia)
Algae Toxicity (static)	7 mg/l (Algae)
1310-73-2 Sodium Hydroxide	
EC50	40.38 mg/kg (Water Flea)

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- **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.*

14 Transport information

· UN-Number	
· ADG, IMDG, IATA	<i>not regulated</i>
· UN proper shipping name	
· ADG, IMDG, IATA	<i>not regulated</i>
· Transport hazard class(es)	
· ADG, ADN, IMDG, IATA	
· Class	<i>not regulated</i>
· Packing group	
· ADG, IMDG, IATA	<i>not regulated</i>
· Environmental hazards:	<i>Not applicable.</i>
· Special precautions for user	<i>Not Applicable</i>
· Transport in bulk according to Annex II of Marpol and the IBC Code	<i>Not applicable.</i>
· UN "Model Regulation":	<i>not regulated</i>

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.

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· Australian Inventory of Industrial Chemicals	
56-81-5	Glycerin
7732-18-5	Water
112926-00-8	Synthetic Amorphous Silica
50-70-4	Sorbitol
87-99-0	Xylitol
	Trade Secret
119-36-8	methyl salicylate
151-21-3	Sodium Lauryl Sulfate
8006-90-4	Oils, Peppermint
11138-66-2	Xanthan Gum
7681-49-4	Sodium Fluoride
9003-01-4	Polyacrylic Acid
532-32-1	Sodium Benzoate
1310-73-2	Sodium Hydroxide
89-78-1	Menthol
56038-13-2	Sucralose
2216-51-5	Menthol

· Standard for the Uniform Scheduling of Medicines and Poisons		
119-36-8	methyl salicylate	S4, S5, S6

· 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**

- H227 Combustible liquid.
- H301 Toxic if swallowed.
- H302 Harmful if swallowed.
- H304 May be fatal if swallowed and enters airways.
- H310 Fatal in contact with skin.
- H311 Toxic in contact with skin.
- H312 Harmful in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H361d Suspected of damaging the unborn child.

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

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· **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

Flam. Liq. 4: Flammable liquids – Category 4

Acute Tox. 4: Acute toxicity – Category 4

Acute Tox. 2: Acute toxicity – Category 2

Acute Tox. 3: Acute toxicity – Category 3

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

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

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

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

Repr. 2: Reproductive toxicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Asp. Tox. 1: Aspiration hazard – Category 1

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

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