

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 02.01.2024

Version number 1

Revision: 02.01.2024

1 Identification of the substance/mixture and of the company/undertaking

- **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
- EC Responsible Person*
Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne Germany
Email: infoDE@ultradent.com
Emergency Phone: +49(0)2203-35-92-0
- **Further information obtainable from:** *Customer Service*
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms** *GHS07*
- **Signal word** *Warning*
- **Hazard-determining components of labelling:**
methyl salicylate
Oils, Peppermint
- **Hazard statements**
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.

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· Precautionary statements

- P101 *If medical advice is needed, have product container or label at hand.*
 P102 *Keep out of reach of children.*
 P103 *Read carefully and follow all instructions.*
 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/information on ingredients

· Mixtures
· Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

CAS: 56-81-5 EINECS: 200-289-5	Glycerin substance with a Community workplace exposure limit	>20-<40%
CAS: 119-36-8 EINECS: 204-317-7	methyl salicylate ⚠ Repr. 2, H361d; ⚠ Acute Tox. 4, H302; Skin Sens. 1B, H317; Aquatic Chronic 3, H412 ATE: LD50 oral: 890 mg/kg	>0.1-<5%
CAS: 151-21-3 EINECS: 205-788-1	Sodium Lauryl Sulfate ⚠ Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; Aquatic Chronic 3, H412	>0.1-<5%
CAS: 8006-90-4 EINECS: 282-015-4	Oils, Peppermint ⚠ Asp. Tox. 1, H304; ⚠ Aquatic Chronic 2, H411; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	<1%
CAS: 7681-49-4 EINECS: 231-667-8	Sodium Fluoride ⚠ Acute Tox. 3, H301; Acute Tox. 2, H310; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319, EUH032	<1%
CAS: 1310-73-2 EINECS: 215-185-5	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

· Description of 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.

· Most important symptoms and effects, both acute and delayed No further relevant information available.

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- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **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).
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

- **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.
- **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 container tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

56-81-5 Glycerin

WEL Long-term value: 10 mg/m³

1310-73-2 Sodium Hydroxide

WEL Short-term value: 2 mg/m³

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

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- **Exposure controls**
- **Appropriate engineering controls** No further data; see item 7.
- **Individual protection measures, such as 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.
 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.
- **Hand protection**



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/face protection**



Tightly sealed goggles

- **Body protection:** Protective work clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Fluid
- **Colour:** According to product specification
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.
- **Boiling point or initial boiling point and boiling range** Undetermined.
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** 177 °C
- **Decomposition temperature:** Not determined.

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· pH at 20 °C	6.3-7.6
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Partly soluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C:	1.214 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.

· Other information	
· Appearance:	
· Form:	Fluid
· Important information on protection of health and environment, and on safety.	
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not determined.

· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

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.

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· **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

· **Information on hazard classes as defined in Regulation (EC) No 1272/2008**· **Acute toxicity** Based on available data, the classification criteria are not met.· **LD/LC50 values relevant for classification:**

ATE (Acute Toxicity Estimates)

Oral	LD50	10,870-11,984 mg/kg
Dermal	LD50	70,000 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)

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)
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)
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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)

· **Serious eye damage/irritation** Causes serious eye irritation.· **Respiratory or skin sensitisation** May cause an allergic skin reaction.

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· **Information on other hazards**· **Endocrine disrupting properties**

None of the ingredients is listed.

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 SulfateEC50 (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)

· **Persistence and degradability** No further relevant information available.· **Bioaccumulative potential** No further relevant information available.· **Mobility in soil** No further relevant information available.· **Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.· **Endocrine disrupting properties** The product does not contain substances with endocrine disrupting properties.· **Other adverse effects**· **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.

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.

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14 Transport information

· UN number or ID number · ADR, IMDG, IATA	not regulated
· UN proper shipping name · ADR, IMDG, IATA	not regulated
· Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	not regulated
· Packing group · ADR, IMDG, IATA	not regulated
· Environmental hazards:	Not applicable.
· Special precautions for user	Not Applicable
· Maritime transport in bulk according to IMO instruments	Not applicable.
· UN "Model Regulation":	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.
· 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**
- H301 Toxic if swallowed.
- H302 Harmful if swallowed.
- H304 May be fatal if swallowed and enters airways.
- H310 Fatal 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.
- H361d Suspected of damaging the unborn child.
- H411 Toxic to aquatic life with long lasting effects.
- H412 Harmful to aquatic life with long lasting effects.
- EUH032 Contact with acids liberates very toxic gas.
- **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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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

Acute Tox. 3: Acute toxicity – Category 3

Acute Tox. 4: Acute toxicity – Category 4

Acute Tox. 2: Acute toxicity – Category 2

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

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

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

Repr. 2: Reproductive toxicity – Category 2

Asp. Tox. 1: Aspiration hazard – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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

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