

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

Printing date 22.01.2020

Revision: 23.10.2019

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

- **Product identifier**
- **Trade name:** Opalescence™ Whitening Toothpaste
- **Article number:** 11577, 1008310
- **Index number:** SDS 12-001.10
- **Relevant identified uses of the substance or mixture and uses advised against** Toothpaste
- **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 Westhoyer 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**



GHS07

Eye Irrit. 2 H319 Causes serious eye irritation.

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a cosmetic in the finished state used in direct physical contact with the human body according to Art. 1.5 (c). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6b), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard statements**
H319 Causes serious eye irritation.
- **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.
P264	Wash thoroughly after handling.

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- P280 *Wear 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.*
 P337+P313 *If eye irritation persists: Get medical advice/attention.*
- **Additional information:**
 Contains Oils, Peppermint. May produce an allergic reaction.
 - **Other hazards**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

3 Composition/information on ingredients

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

- **Dangerous components:**

CAS: 56-81-5 EINECS: 200-289-5	Glycerine substance with a Community workplace exposure limit	<35%
CAS: 112926-00-8 EC number: 601-214-2	Synthetic Amorphous Silica ⚠ Acute Tox. 3, H331	>10-≤25%
CAS: 119-36-8 EINECS: 204-317-7	Methyl Salicylate ⚠ Acute Tox. 4, H302	≤2.5%
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	≤2.5%
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	0.25%
CAS: 1310-73-2 EINECS: 215-185-5	Sodium Hydroxide ⚠ Acute Tox. 3, H301; ⚠ Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H312	<0.5%

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

4 First aid measures

- **Description of first aid measures**
- **After inhalation:** This product is a viscous gel, therefore chance of inhalation is extremely low.
- **After skin contact:** Rinse with water and soap.
- **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.
 If symptoms persist consult doctor.
- **Information for 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:**
Dry Chemical
Water spray
Water mist
Water fog
Foam, dry chemical, carbon dioxide
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:** Wear fully protective suit.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **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:** No special precautions are necessary if used correctly.
- **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:**
See product labelling.
Keep container tightly sealed.
- **Specific end use(s)** Toothpaste

8 Exposure controls/personal protection

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

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· **Control parameters**· **Ingredients with limit values that require monitoring at the workplace:****56-81-5 Glycerine**WEL (Great Britain) Long-term value: 10 mg/m³**1310-73-2 Sodium Hydroxide**WEL (Great Britain) Short-term value: 2 mg/m³· **Additional information:** The lists valid during the making 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.

Avoid contact with the eyes and skin.

· **Respiratory protection:** Not required.· **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

· **Information on basic physical and chemical properties**· **General Information**· **Appearance:**

Form: Gel

Colour: Green

· **Odour:** Mint· **Odour threshold:** Not determined.

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· pH-value:	6.3-7.6
· Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
· Flash point:	Not applicable.
· 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.
· 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:	Not miscible or difficult to mix.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	<50 %
Water:	<40 %
VOC (EC)	0.00 %
· 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:**
 - Light
 - Ignition sources
 - Heat
- **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 Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Oral	LD50	11,104-12,270 mg/kg
Dermal	LD50	70,000 mg/kg (rabbit)
Inhalative	LC50/4 h	>0.355 mg/l (rat)

56-81-5 Glycerine

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)
Inhalative	LC50/4 h	>0.1425 mg/l (rat)

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)

119-36-8 Methyl Salicylate

Oral	LD50	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)

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- **Primary irritant effect:**
- **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** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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 Glycerine	
EC50	>10,000 mg/l (Bacteria) >10,000 mg/l (daphnia)
119-36-8 Methyl Salicylate	
Aqua toxicity	1.6 mg/l (Algae)
EC50	28 mg/l (daphnia)
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/l (Water Flea)

- **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.

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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-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.
· Transport in bulk according to Annex II of Marpol 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**
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **Chemical safety assessment:**
The product meets 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.

- **Relevant phrases**
- 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.

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*H319 Causes serious eye irritation.**H331 Toxic if inhaled.**H411 Toxic to aquatic life with long lasting effects.**H412 Harmful to aquatic life with long lasting effects.*· **Department issuing SDS:** Regulatory Affairs· **Contact:** Customer Service· **Abbreviations and acronyms:***ADR: Accord européen sur le transport 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)**VOC: Volatile Organic Compounds (USA, EU)**LC50: Lethal concentration, 50 percent**LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Acute Tox. 4: Acute toxicity - oral – Category 4**Acute Tox. 2: Acute toxicity - dermal – Category 2**Acute Tox. 3: Acute toxicity - inhalation – 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**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**Skin Sens. 1: Skin sensitisation – Category 1**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*

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