

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

Printing date 16.11.2022

Version number 1

Revision: 16.11.2022

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

- **Product identifier**
- **Trade name:** *Opalescence™ Whitening Toothpaste*
- **Article number:** *SDS 12-001.12, 1008310, 11577*
- **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 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.

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** *Void*
- **Hazard pictograms** *GHS07*
- **Signal word** *Warning*
- **Hazard statements**
H319 Causes serious eye irritation.
- **Precautionary statements**

<i>P101</i>	<i>If medical advice is needed, have product container or label at hand.</i>
<i>P102</i>	<i>Keep out of reach of children.</i>
<i>P103</i>	<i>Read carefully and follow all instructions.</i>
<i>P264</i>	<i>Wash thoroughly after handling.</i>
<i>P280</i>	<i>Wear eye protection / face protection.</i>
<i>P305+P351+P338</i>	<i>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</i>

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P337+P313

If eye irritation persists: Get medical advice/attention.

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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: 112926-00-8 EC number: 601-214-2	Synthetic Amorphous Silica ⚠ Acute Tox. 3, H331	>10-<30%
CAS: 119-36-8 EINECS: 204-317-7	Methyl Salicylate ⚠ Acute Tox. 4, H302	>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	≥1-<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, 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**
- **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.
- **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 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.

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- **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:**
 - 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).
- **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:** 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

- **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.

- **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:** Not required.

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· **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.
· 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.

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- **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.
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- **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** 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.

11 Toxicological information

- **Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity**

· **LD/LC50 values relevant for classification:**

ATE (Acute Toxicity Estimates)

Oral	LD50	11,104-12,270 mg/kg
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Dermal	LD50	70,000 mg/kg
Inhalative	LC50/4 h	2.58 mg/l

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)

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	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.

· **Information on other hazards**

· **Endocrine disrupting properties**

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)
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)

- **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.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

- **UN number or ID number**
- **ADR, IMDG, IATA** not regulated

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· UN proper shipping name · ADR, IMDG, IATA	<i>not regulated</i>
· Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	<i>not regulated</i>
· Packing group · ADR, IMDG, IATA	<i>not regulated</i>
· Environmental hazards:	<i>Not applicable.</i>
· Special precautions for user	<i>Not Applicable</i>
· Maritime transport in bulk according to IMO instruments	<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**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **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 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.*
 H331 *Toxic if inhaled.*
 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*
- **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

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*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**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**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*

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

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