

Safety Data Sheet

according to WHS Regulations

Printing date 27.07.2023

Revision: 27.07.2023

1 Identification

- **Product identifier**
- **Trade name:** *Opalescence™ Whitening Toothpaste*
- **Article number:** *SDS 12-001.12R02, 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
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** *Void*
- **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.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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

- **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:**
This product is a viscous gel, therefore chance of inhalation is extremely low.
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:**
Rinse with water and soap.
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 swallowed in large quantities seek medical attention.
- **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 Fire Fighting Measures

- **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.
- **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).
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:**
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:**
See product labelling.
Keep container tightly sealed.
- **Specific end use(s)** Toothpaste

8 Exposure controls and personal protection

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

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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.

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

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| | |
|---|---|
| · 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. |
| · 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 Stable**
- **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 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 |

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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) |
| | 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) |
| 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.

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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.

· **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.

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

14 Transport information

· **UN-Number**

· **ADG, IMDG, IATA**

not regulated

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| | |
|---|-----------------|
| · UN proper shipping name | |
| · ADG, IMDG, IATA | not regulated |
| · Transport hazard class(es) | |
| · ADG, ADN, IMDG, IATA | |
| · Class | not regulated |
| · Packing group | |
| · ADG, 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**· **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 |
| 12001-26-2 | Mica |
| 2216-51-5 | Menthol |
| 13463-67-7 | Titanium Dioxide |

· **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.

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- **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**

- 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

- **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
- 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.**