



Safety Data Sheet according to WHS Regulations

Date of issue: 28.03.2025

Revision: 28.03.2025

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1 Identification

- **Other means of identification**
- **Trade name:** Opalescence™ Home Advanced Tooth Whitening 10%
- **Article number:** SDS 499-001.03R01, 1008679, 1012433, 5477, 5821-US, 6005-US, 6007-US
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **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) : +1 (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) Identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonised System (GHS).
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void

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%
	⚠ Eye damage/irritation – Category 2A, H319	
7722-84-1	Hydrogen Peroxide	≤10%
	⚠ Oxidising liquids - Category 1, H271; ⚠ Skin corrosion/irritation – Category 1A, H314; ⚠ Acute toxicity - oral – Category 4, H302; Acute toxicity - inhalation – Category 4, H332	

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1310-58-3	Potassium Hydroxide	>1-<10%
	⚠ Skin corrosion/irritation – Category 1A, H314; ⚠ Acute toxicity - oral – Category 4, H302	
7758-11-4	Dipotassium Phosphate	>1-<10%
	⚠ Acute toxicity - inhalation – Category 3, H331	

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

4 First Aid Measures

- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **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.

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:** Pick up mechanically.
- **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.
No special measures required.
- **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:** None.
- **Specific end use(s)** No further relevant information available.

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8 Exposure controls and personal protection

· **Appropriate engineering controls** No further data; see section 7.

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

56-81-5 Glycerin

TWA Short-term value: 10 mg/m³

WES Long-term value: 10 mg/m³
inhalable dust

7722-84-1 Hydrogen Peroxide

WES Long-term value: 1.4 mg/m³, 1 ppm

1310-58-3 Potassium 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:**

The usual precautionary measures are to be adhered to when handling chemicals.

· **Respiratory protection:** Not required.

· **Protection of hands:**

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:** Not required.

· **Body protection:** Protective work clothing

9 Physical and Chemical Properties

· **General Information**

· **Appearance:**

· **Form:** Gel

· **Colour:** White Opaque

· **Odour:** Mint

· **Odour threshold:** Not determined.

· **pH-value at 20 °C:** 5-7

· **Change in condition**

· **Melting point/freezing point:** Undetermined.

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

· **Flash point:** Not applicable.

· **Flammability** Not determined.

· **Decomposition temperature:** Not determined.

· **Ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

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- **Explosion limits:**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Vapour pressure:** Not applicable.
- **Density at 20 °C:** 1.3 g/cm³
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Evaporation rate** Not applicable.
- **Solubility in / Miscibility with**
- **water:** Insoluble.
- **Partition coefficient: n-octanol/water:** Not determined.
- **Viscosity:**
- **Dynamic:** Not applicable.
- **Kinematic:** Not applicable.
- **Other information**
- **Particle characteristics** Not determined.
- **Physical state** Solid

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	3,091 mg/kg
Inhalative	LC50/4 h	>39.7 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	LD50	>5,000 mg/l (Fish)
		>21,900 mg/kg (rat)
		10,000 mg/kg (rabbit)
		>0.1425 mg/l (rat)
Inhalative	LC50/4 h	>0.1425 mg/l (rat)

7722-84-1 Hydrogen Peroxide

Oral	LC50 Fish	16.4 mg/l (Fish)
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1310-58-3 Potassium Hydroxide

Oral	LD50	214 mg/kg (rat)
	LC50 Fish	80 mg/l (Fish)

7758-11-4 Dipotassium Phosphate

Oral	LD50	4,260-5,700 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)
Inhalative	LC50/4 h	>0.83 mg/l (rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **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)
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7722-84-1 Hydrogen Peroxide

EC50	1.38 mg/l (Algae)
	2.4 mg/l (daphnia)

- **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.

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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|---|-----------------|
| · UN-Number | |
| · ADG, IMDG, IATA | not regulated |
| · UN proper shipping name | |
| · ADG, ADN, 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**

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

- **Australian Inventory of Industrial Chemicals**

All ingredients are listed.

- **Standard for the Uniform Scheduling of Medicines and Poisons**

7722-84-1	Hydrogen Peroxide	S5, S6, S10
1310-58-3	Potassium Hydroxide	S5, S6, S10

- **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**

H271 May cause fire or explosion; strong oxidizer.

H302 Harmful if swallowed.

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*H314 Causes severe skin burns and eye damage.**H319 Causes serious eye irritation.**H331 Toxic if inhaled.**H332 Harmful if inhaled.*

- **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

NIOSH: National Institute for Occupational Safety

Oxidising liquids - Category 1: Oxidizing liquids – Category 1

Acute toxicity - oral – Category 4: Acute toxicity – Category 4

Acute toxicity - inhalation – Category 3: Acute toxicity – Category 3

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

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

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

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