Safety Data Sheet
according to WHS Regulations

Date of issue: 03.03.2025 Revision: 03.03.2025

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1 Identification

· **Other means of identification**

· **Trade name: Opalescence™ Home Advanced Tooth Whitening 10%**

· **Article number:** SDS 499-001.02R01, 1008679, 1007940, 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) :(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 Eye damage/irritation – Category 2A, H319	>20-<40%
7722-84-1	Hydrogen Peroxide Oxidising liquids - Category 1, H271; Skin corrosion/irritation – Category 1A, H314; Acute toxicity - oral – Category 4, H302; Acute toxicity - inhalation – Category 4, H332	9.5-11.6%

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

· **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	3,082-3,091 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)
	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)

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)
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.***