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1 Identification

- · Other means of identification
- · Trade name: Opalescence™ Office-Mixed
- · Article number: SDS 351-001.06R01, 71195, 71194, 47409, 4740-EU, 4757-EU, 4759-EU
- Relevant identified uses of the substance or mixture and uses advised against Professional Dental Bleaching Gel
- · Application of the substance / the mixture Professional Dental Bleaching Gel
- · 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

on line order support @ultradent.com

(800) 552-5512

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



Eye damage/irritation - Category 2A H319 Causes serious eye irritation.

- · Label elements
- · GHS label elements Void
- · 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.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.

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P337+P313 If eye irritation persists: Get medical advice/attention.

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3 Composition and Information on Ingredients

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

· Dangerous components:			
56-81-5	Glycerin	>50-<70%	
	♦ Eye damage/irritation – Category 2A, H319		
	Hydrogen Peroxide	6%	
	Oxidising liquids - Category 1, H271; Skin corrosion/irritation – Category 1A, H314; Acute toxicity - oral – Category 4, H302; Acute toxicity - inhalation – Category 4, H332		

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

4 First Aid Measures

- · After inhalation: This product is a viscous gel, therefore chance of inhalation is not possible.
- · After skin contact: Generally the product does not irritate the skin.
- · After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · 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:
- 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: See product labeling.
- · Information about fire and explosion protection: No special measures required.

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- · 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) Professional Dental Bleaching Gel

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

- · 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: 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

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· Body protection: Protective work clothing

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9 Physical and Chemical Properties

· General Information

· Appearance:

· Form: Gel

Colour: Red-brown
Odour: Odourless
Odour threshold: Not determined.

• pH-value at 20 °C: 6.8-8.2

· Change in condition

Melting point/freezing point:
 Initial boiling point and boiling range:
 Flash point:
 Flammability
 Decomposition temperature:
 Undetermined.
 Not applicable.
 Not determined.

• 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: 1.2-1.3 g/cm³
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

• Particle characteristics Not applicable.

· Physical state Fluid

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.

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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	· LD/LC50 values relevant for classification:				
ATE (Acu	ATE (Acute Toxicity Estimates)				
Oral	LD50	9,259 mg/kg			
Inhalative	LC50/4 h	204 mg/l			
56-81-5 G	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)			
7722-84-1	7722-84-1 Hydrogen Peroxide				
Oral	LC50 Fish	16.4 mg/l (Fish)			

- 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.
- · 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.

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- · 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.

IIN Normal on		
UN-Number ADG, ADN, 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, ĬMDG, IATA	not regulated	
Environmental hazards:	Not applicable.	
Special precautions for user	Not Applicable	
Transport in bulk according to Annex I	I of Marpol	
and the IBC Code	Not applicable.	
UN "Model Regulation":	not regulated	

15 Regulatory information

9003-39-8 Polyvinylpyrrolidone 7757-79-1 Potassium Nitrate

- · 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

 56-81-5 Glycerin

 7732-18-5 Water

 7722-84-1 Hydrogen Peroxide

 Trade Secret

 9003-01-4 Polyacrylic Acid

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	7681-49-4	Sodium Fluoride		
Ī	1310-73-2	Sodium Hydroxide		
	6381-92-6	Edetate Disodium		
Ī	1332-37-2	Red Iron Oxide		
	1317-61-9	Iron Oxide Black		
· Standard for the Uniform Scheduling of Medicines and Poisons				
	7722-84-1	Hydrogen Peroxide 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:

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

H271 May cause fire or explosion; strong oxidizer.

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H319 Causes serious eye irritation.

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

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.