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Safety Data Sheet according to WHS Regulations

Printing date 03.08.2023

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Revision: 03.08.2023

	oduct identifier
1	rade name: <u>OpalescenceTM TrèswhiteTM Supreme, Opalescence GoTM (Mint or Melon PF 10-15% HP)</u>
R P	rticle number: SDS 372-001.04R02, 15053, 71048, 15054. elevant identified uses of the substance or mixture and uses advised against ^r ofessional Dental Teeth Whitening Gel oplication of the substance / the mixture Professional Dental Teeth Whitening Gel
MU5 SU OULSAE	etails of the supplier of the safety data sheet fanufacturer/Supplier: Itradent Products, Inc. D5 W. Ultradent Drive (10200 S) outh Jordan, UT 84095-3942 SA Itradent support@ultradent.com Itradent Australia Pty Ltd. Evel 22/2 Market Street odney NSW 2000 Istralia nail: info.anz@ultradent.com oll Free: 1-800-290929
F C N N E	<i>urther information obtainable from:</i> <i>ustomer Service</i> <i>one</i> <i>mergency telephone number:</i> <i>HEMTREC (NORTH AMERICA) :(800) 424-9300</i> <i>(INTERNATIONAL) : +(703) 527-3887</i>

· Classification of the substance or mixture



Skin Corr. 1A H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.



Acute Tox. 4 H302 Harmful if swallowed.

- · Label elements
- · GHS label elements Void
- · Hazard pictograms GHS05, GHS07
- · Signal word Danger

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· Hazard-determini	ng components of labelling:
Hydrogen Peroxid	
Carbamide Peroxi	
Sodium Hydroxide	
Sodium Fluoride	
· Hazard statements	S
H302 Harmful if s	wallowed.
H314 Causes seve	re skin burns and eye damage.
· Precautionary stat	tements
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.
P260	Do not breathe dusts or mists.
<i>P303+P361+P35</i> .	3 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351+P338	8 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if
	present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P321	Specific treatment (see on this label).
P405	Store locked up.
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.

56-81-5	Glycerin	30-60%	
	🚸 Serious eye damage/irritation – Category 2A, H319		
7722-84-1	Hydrogen Peroxide	10-<30%	
	𝕸 Ox. Liq. 1, H271; �◊ Skin Corr. 1A, H314; �◊ Acute Tox. 4, H302; Acute Tox. 4, H332	-	
124-43-6	Carbamide Peroxide	≥5-<10%	
	🚸 Ox. Sol. 3, H272; 🚸 Skin Corr. 1B, H314; Eye Dam. 1, H318		
1310-73-2	Sodium Hydroxide	≥3-<5%	
7757-79-1	Potassium Nitrate	<10%	
	(a) Ox. Sol. 2, H272; (b) Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H335-H336		
	Artificial Watermelon	<10%	
	🚸 Flam. Liq. 3, H226	1	
8006-90-4	Oils, Peppermint	≥ 0.1-<19	
	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	<10%	
	Acute Tox. 3, H301; Acute Tox. 2, H310; (1) Skin Irrit. 2, H315; Serious eye damage/ irritation – Category 2A, H319		

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

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4 First Aid Measures

• General information:

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

• After inhalation:

This product is a viscous gel, therefore chance of inhalation is extremely low.

Seek medical treatment in case of complaints.

In case of unconsciousness place patient stably in side position for transportation.

• After skin contact:

If skin irritation continues, consult a doctor.

Immediately wash with water and soap and rinse thoroughly.

· After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.

• After swallowing:

If swallowed in large quantities seek medical attention.

Call for a doctor immediately.

Drink plenty of water and provide fresh air. Call for a doctor immediately.

- 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

- During heating or in case of fire poisonous gases are produced.
- **Protective equipment:** Wear fully protective suit. Mouth respiratory protective device.

6 Accidental Release Measures

Personal precautions, protective equipment and emergency procedures Mount respiratory protective device.
Wear protective equipment. Keep unprotected persons away.
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). Use neutralising agent. 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.

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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: Keep respiratory protective device available.
- 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 Teeth Whitening Gel

8 Exposure controls and personal protection

• Additional information about design of technical facilities: No further data; see item 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

1310-73-2 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.

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· 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

General Information	
Appearance:	
Form:	Gel
Colour:	Colorless to White
Odour:	Product specific
Odour threshold:	Not determined.
pH-value at 20 °C:	5.2-7.4
Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	· Undetermined.
Flash point:	Not applicable.
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:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
water:	Not miscible or difficult to mix.
Partition coefficient: n-octanol/water:	Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.

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: Excess heat

· Incompatible materials: Strong caustics, most metals

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· Hazardous decomposition products: No dangerous decomposition products known.

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I			
	formation on toxicological effects ute toxicity Harmful if swallowed. D/LC50 values relevant for classification:		
	ute Toxicity Estimates)		
Oral	LD50	1,774-2,676 mg/kg	
Dermal	LD50	33,750 mg/kg	
Inhalative	e LC50/4 h	85.9 mg/l	
56-81-5 (Ilycerin		
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 Hydrogen Peroxide		
Oral	LC50 Fish	16.4 mg/l (Fish)	
124-43-6 Carbamide Peroxide			
Oral	LD50	>2,000 mg/kg (rat)	
1310-73	10-73-2 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)	
7757-79-	1 Potassium Nitrate	·	
Oral	LD50	3,015 mg/kg (rat)	
		1,901 mg/kg (rabbit)	
	LC50 Fish	1,378 mg/l (Fish)	
Dermal	LD50	>5,000 mg/kg (rat)	
	LC50(Daphnia magna)	490 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)	

• Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

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· 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
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• Aquatic toxicity:		
56-81-5 Glycerin		
EC50	>10,000 mg/kg (Bacteria)	
7722-84-1 Hydrogen I	Peroxide	
EC50	1.38 mg/l (Algae)	
	2.4 mg/l (daphnia)	
1310-73-2 Sodium Hydroxide		
EC50 40.38 mg/kg (Water Flea)		
7681-49-4 Sodium Fli	uoride	
EC50	272 mg/kg (Algae)	
	98 mg/kg (daphnia)	
Algae Toxicity (static)	7 mg/l (Algae)	
· Persistence and degra	dability No further relevant information available.	
· Rehaviour in environ	mental systems.	

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 2 (German Regulation) (Self-assessment): hazardous for water Do not allow product to reach ground water, water course or sewage system. Must not reach sewage water or drainage ditch undiluted or unneutralised. Danger to drinking water if even small quantities leak into the ground.

· 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.*

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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, IMDG, 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.	

15 Regulatory information

Australian I	Inventory of Industrial Chemicals		
7732-18-5	Water		
56-81-5	Glycerin		
7722-84-1	Hydrogen Peroxide		
9003-01-4	Polyacrylic Acid		
124-43-6	Carbamide Peroxide		
1310-73-2	Sodium Hydroxide		
7757-79-1	Potassium Nitrate		
9003-39-8	Polyvinylpyrrolidone		
	Trade Secret		
87-99-0	Xylitol		
7558-79-4	Sodium Phosphate, Dibasic		
8006-90-4	Oils, Peppermint		
56038-13-2	Sucralose		
7681-49-4	Sodium Fluoride		
6381-92-6	Edetate Disodium		
151-21-3	Sodium Lauryl Sulfate		
Standard fo	r the Uniform Scheduling of Medicines and Poisons		
7722-84-1	Hydrogen Peroxide	S5, S6, S1	
124-43-6	Carbamide Peroxide	S5, S6, S1	
7558-79-4	Sodium Phosphate, Dibasic	<i>S3, S4</i>	

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• 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

H226 Flammable liquid and vapour. H227 Combustible liquid. H271 May cause fire or explosion; strong oxidizer. H272 May intensify fire; oxidizer. 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. H332 Harmful if inhaled. H335 May cause respiratory irritation. H336 May cause drowsiness or dizziness. · 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. 3: Flammable liquids – Category 3 Flam. Liq. 4: Flammable liquids - Category 4 Ox. Liq. 1: Oxidizing liquids – Category 1 Ox. Sol. 2: Oxidizing solids – Category 2 Ox. Sol. 3: Oxidizing solids – Category 3 Acute Tox. 3: Acute toxicity - Category 3 Acute Tox. 4: Acute toxicity - Category 4 Acute Tox. 2: Acute toxicity – Category 2 Skin Corr. 1A: Skin corrosion/irritation - Category 1A Skin Corr. 1B: Skin corrosion/irritation - Category 1B 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 STOT SE 3: Specific target organ toxicity (single exposure) - Category 3

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Asp. Tox. 1: Aspiration hazard – Category 1 • * **Data compared to the previous version altered.** (Contd. of page 9)

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