Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 02.08.2018 *Revision: 16.05.2018*

1 Identification of the substance/mixture and of the company/undertaking

· **Product identifier**

· **Trade name: Opalescence® Quick PF 45%**

· **Article number:** 15073
· **Index number:** SDS 89-001.08
· **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Teeth Whitening Gel
· **Application of the substance / the mixture** Professional Dental Teeth Whitening 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
onlineordersupport@utradent.com

EC Responsible Person
Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne Germany
Email: infoDe@ultradent.com
Emergency Phone: +49(0)2203-35-92-0

· **Further information obtainable from:** Customer Service
· **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) :(800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

· **Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**

GHS07

Acute Tox. 4 H302 Harmful if swallowed.
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.

· **Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
· **Hazard pictograms**

GHS07

· **Signal word** Warning

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· **Hazard-determining components of labelling:**
Carbamide Peroxide
Hydrogen Peroxide
Sodium Hydroxide
Sodium Fluoride
· **Hazard statements**
H302 Harmful if swallowed.
H315 Causes skin irritation.
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.
P280	Wear protective gloves / eye protection / face protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P330	Rinse mouth.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Additional information:**
Contains Oils, Peppermint. May produce an allergic reaction.
· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

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

· **Dangerous components:**

CAS: 56-81-5 EINECS: 200-289-5	Glycerine substance with a Community workplace exposure limit	< 25%
CAS: 124-43-6 EINECS: 204-701-4	Carbamide Peroxide Ox. Sol. 3, H272; Skin Corr. 1B, H314	≤20%
CAS: 7722-84-1 EINECS: 231-765-0	Hydrogen Peroxide Ox. Liq. 1, H271; Skin Corr. 1A, H314; Acute Tox. 4, H302; Acute Tox. 4, H332	< 10%
CAS: 25322-68-3 NLP: 500-038-2	Polyethylene Glycol Acute Tox. 2, H330	< 10%
CAS: 1310-73-2 EINECS: 215-185-5	Sodium Hydroxide Acute Tox. 3, H301; Acute Tox. 4, H312	< 5%
CAS: 7757-79-1 EINECS: 231-818-8	Potassium Nitrate Ox. Sol. 3, H272	≤3%
CAS: 7681-49-4 EINECS: 231-667-8	Sodium Fluoride Acute Tox. 3, H301; Acute Tox. 2, H310; Skin Irrit. 2, H315; Eye Irrit. 2, H319	≤1.1%

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CAS: 8006-90-4 EINECS: 282-015-4	Oils, Peppermint Asp. Tox. 1, H304; Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	≤0.5%

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

4 First aid measures

· **Description of first aid measures**
· **General information:**
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 not possible.
· **After skin contact:** 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.
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 Firefighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
Water spray
Use fire extinguishing methods suitable to surrounding conditions.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** Wear self-contained respiratory protective device.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Not required.
· **Environmental precautions:** No special measures required.
· **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** No special precautions are necessary if used correctly.
· **Information about fire - and explosion protection:** No special measures required.

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· **Conditions for safe storage, including any incompatibilities**
· **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/personal protection

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

· **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**	
56-81-5 Glycerine	
WEL	Long-term value: 10 mg/m³
7722-84-1 Hydrogen Peroxide	
WEL	Short-term value: 2.8 mg/m³, 2 ppm Long-term value: 1.4 mg/m³, 1 ppm

· **Additional information:** The lists valid during the making were used as basis.

· **Exposure controls**
· **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 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.

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· **Eye protection:**

Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Gel
Colour:	Colourless
· **Odour:**	Mint
· **Odour threshold:**	Not determined.
· **pH-value at 20 °C:**	5.6-7.2
· **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 at 20 °C:**	1.27 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.
· **Solvent content:**	
Organic solvents:	< 25 %
Water:	< 25 %
VOC (EC)	0.00 %

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· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **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**
Harmful if swallowed.

· **LD/LC50 values relevant for classification:**

ATE (Acute Toxicity Estimates)		
Oral	LD50	1,157-2,496 mg/kg
Dermal	LD50	11,602 mg/kg
Inhalative	LC50/4 h	>0.62 mg/l

56-81-5 Glycerine		
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)

124-43-6 Carbamide Peroxide		
Oral	LD50	>2,000 mg/kg (rat)

25322-68-3 Polyethylene Glycol		
Oral	LD50	19,600 mg/kg (Guinea pig)
		17,300 mg/kg (mouse)
		>10,000 mg/kg (rat)
	LC50 Fish	>100 mg/l (Fish)
Dermal	LD50	>20,000 mg/kg (rabbit)
Inhalative	LC50/4 h	1.65 mg/l (rat)
	LC50(Daphnia magna)	>10,000 mg/l (Water Flea) (Toxicity to aquatic invertebrates)

1310-73-2 Sodium Hydroxide		
Oral	LD50	130-340 mg/kg (rat)
	LC50 Fish	160 mg/l (Fish)

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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)
7681-49-4 Sodium Fluoride		
Oral	LD50	26-101 mg/kg (mouse)
		32 mg/kg (rat)
	LC50 Fish (static)	17 mg/l (Fish)
Dermal	LD50	175 mg/kg (rat)
8006-90-4 Oils, Peppermint		
Oral	LD50	2,490 mg/kg (mouse)
		2,426 mg/kg (rat)

· **Primary irritant effect:**
· **Skin corrosion/irritation**
Causes skin irritation.
· **Serious eye damage/irritation**
Causes serious eye irritation.
· **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
· **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 Glycerine	
EC50	>10,000 mg/l (Bacteria)
	>10,000 mg/l (daphnia)
1310-73-2 Sodium Hydroxide	
EC50	40.38 mg/l (Water Flea)
7681-49-4 Sodium Fluoride	
EC50	272 mg/kg (Algae)
	98 mg/kg (daphnia)
Algae Toxicity (static)	7 mg/l (Algae)

· **Persistence and degradability** No further relevant information available.
· **Behaviour in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.

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· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:** Not known to be hazardous to water.
· **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**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**	
HP 6	Acute Toxicity
HP 8	Corrosive

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

14 Transport information

· **UN-Number** · **ADR, ADN, IMDG, IATA**	not regulated
· **UN proper shipping name** · **ADR, ADN, IMDG, IATA**	not regulated
· **Transport hazard class(es)** · **ADR, ADN, IMDG, IATA** · **Class**	not regulated
· **Packing group** · **ADR, 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**

· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** None of the ingredients is listed.
· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

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· ***Chemical safety assessment:***
Device is biocompatible when used as directed by dental professionals per ISO 10993-1

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***
H271 May cause fire or explosion; strong oxidiser.
H272 May intensify fire; oxidiser.
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.
H319 Causes serious eye irritation.
H330 Fatal if inhaled.
H332 Harmful if inhaled.
H411 Toxic to aquatic life with long lasting effects.

· ***Department issuing SDS:*** *Regulatory Affairs*
· ***Contact:*** *Customer Service*
· ***Abbreviations and acronyms:***
ADR: Accord européen sur le transport 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
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
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)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Ox. Liq. 1: Oxidizing liquids – Category 1
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 Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Asp. Tox. 1: Aspiration hazard – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2