

Safety data sheet according to UK REACH

Printing date 21.07.2025

Version number 1

Revision: 21.07.2025

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

- **Product identifier**
- **Trade name:** Opalescence™ F 15% Melon
- **Article number:** SDS 16-001.12R01, 39305, 14429, 14435, 3994, 3995
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Teeth Bleaching Gel
- **Application of the substance / the mixture** Professional Dental Teeth 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
onlineordersupport@ultradent.com
(800) 552-5512
- **EC Responsible Person**
Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne Germany
Email: infoDE@ultradent.com
Office Phone: +49(0)2203-35-92-0
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : +1 (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

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



corrosion

Eye Dam. 1 H318 Causes serious eye damage.



Skin Irrit. 2 H315 Causes skin irritation.

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** GHS05
- **Signal word** Danger
- **Hazard-determining components of labelling:**
Carbamide Peroxide
Sodium Hydroxide

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- **Hazard statements**

H315 Causes skin irritation.

H318 Causes serious eye damage.

- **Precautionary statements**

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read carefully and follow all instructions.

P280 Wear protective gloves / 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.

P310 Immediately call a POISON CENTER/doctor.

P321 Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it before reuse.

P332+P313 If skin irritation occurs: Get medical advice/attention.

3 Composition/information on ingredients

- **Mixtures**

- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 56-81-5 EINECS: 200-289-5	Glycerin substance with a Community workplace exposure limit	<40%
CAS: 124-43-6 EINECS: 204-701-4	Carbamide Peroxide ⚠ Ox. Sol. 3, H272; ⚠ Skin Corr. 1B, H314	>10-≤25%
CAS: 1310-73-2 EINECS: 215-185-5	Sodium Hydroxide ⚠ Skin Corr. 1A, H314	≥1-<5%
	Artificial Watermelon ⚠ Flam. Liq. 3, H226	1-10%
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, EUH032	0.25%

- **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:** Immediately remove any clothing soiled by the product.

- **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.

- **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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- **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 fully protective suit.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment.
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 section 13.
- **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

- **Precautions for safe handling:** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **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 Bleaching Gel

8 Exposure controls/personal protection

- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**

56-81-5 Glycerin

WEL Long-term value: 10 mg/m³

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1310-73-2 Sodium Hydroxide

WEL Short-term value: 2 mg/m³

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

· **Exposure controls**

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

· **Individual protection measures, such as 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 skin.

Avoid contact with the eyes and skin.

· **Respiratory protection:** Not required.

· **Hand protection**



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/face protection**



Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Physical state**

Fluid

· **Colour:**

Colourless

· **Odour:**

Watermelon

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **Boiling point or initial boiling point and boiling range**

Undetermined.

· **Flammability**

Not applicable.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

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· Flash point:	Not applicable.
· Decomposition temperature:	Not determined.
· pH at 20 °C	6-7.2
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Partly soluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C:	1.2-1.3 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Other information	
· Appearance:	
· Form:	Gel
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not determined.
· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

10 Stability and reactivity

- **Reactivity Stable**
- **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:** Excess heat
- **Incompatible materials:** Strong caustics, most metals

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· **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

· **Information on hazard classes as defined in Regulation (EC) No 1272/2008**· **Acute toxicity** Based on available data, the classification criteria are not met.· **LD/LC50 values relevant for classification:**

ATE (Acute Toxicity Estimates)

Oral	LD50	20,800 mg/kg
Dermal	LD50	70,000 mg/kg

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)

124-43-6 Carbamide Peroxide

Oral	LD50	>2,000 mg/kg (rat)
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1310-73-2 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)

7681-49-4 Sodium Fluoride

Oral	LD50	52 mg/kg (mouse)
	LC50 Fish (static)	17 mg/l (Fish)
Dermal	LD50	175 mg/kg (rat)

· **Primary irritant effect:**· **Skin corrosion/irritation** Causes skin irritation.· **Serious eye damage/irritation** Causes serious eye damage.· **Information on other hazards**· **Endocrine disrupting properties**

None of the ingredients is listed.

12 Ecological information

· **Toxicity**· **Aquatic toxicity:**

56-81-5 Glycerin

EC50	>10,000 mg/kg (Bacteria)
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1310-73-2 Sodium Hydroxide

EC50 40.38 mg/kg (Water Flea)

7681-49-4 Sodium FluorideEC50 272 mg/kg (Algae)
98 mg/kg (daphnia)

Algae Toxicity (static) 7 mg/l (Algae)

- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Endocrine disrupting properties** The product does not contain substances with endocrine disrupting properties.
- **Other adverse effects**
- **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.

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.

14 Transport information

- **UN number or ID number**
- **ADR, 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
- **Maritime transport in bulk according to IMO instruments** Not applicable.

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· 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.

· Poisons Act

· Regulated explosives precursors

None of the ingredients is listed.

· Regulated poisons

None of the ingredients is listed.

· Reportable explosives precursors

None of the ingredients is listed.

· Reportable poisons

1310-73-2 Sodium Hydroxide

12% of total caustic alkalinity

7681-49-4 Sodium Fluoride

Listed

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

· Chemical safety assessment:

This product meets the toxicologic requirements of cosmetics per the US Food, Drug, and Cosmetic Act.

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.

H272 May intensify fire; oxidiser.

H301 Toxic if swallowed.

H310 Fatal in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

EUH032 Contact with acids liberates very toxic gas.

· 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

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

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vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
ATE: Acute toxicity estimate values
Flam. Liq. 3: Flammable liquids – Category 3
Ox. Sol. 3: Oxidizing solids – Category 3
Acute Tox. 3: Acute toxicity – Category 3
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
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
· *** Data compared to the previous version altered.**

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