



Safety data sheet according to UK REACH

Printing date 28.03.2025

Version number 1

Revision: 28.03.2025

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

- **Product identifier**
- **Trade name:** Opal™ by Opalescence™ Prefilled Whitening Trays Gentle
- **Article number:** SDS 367-001.02R01, 1011043, 1011572, 5526
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Pre-filled Tooth Whitening Treatment
- **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
- **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**



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 GB CLP regulation.
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard statements**
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 carefully and follow all instructions.
P264 Wash thoroughly after handling.

(Contd. on page 2)

Safety data sheet according to UK REACH

Printing date 28.03.2025

Version number 1

Revision: 28.03.2025

Trade name: Opal™ by Opalescence™ Prefilled Whitening Trays Gentle

(Contd. of page 1)

- 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.
 P332+P313 If skin irritation occurs: Get medical advice/attention.
 P362+P364 Take off contaminated clothing and wash it before reuse.
 P337+P313 If eye irritation persists: 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	>30-<50%
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 Specific concentration limits: Ox. Liq. 1; H271: $C \geq 70\%$ Ox. Liq. 2; H272: $50\% \leq C < 70\%$ Skin Corr. 1A; H314: $C \geq 70\%$ Skin Corr. 1B; H314: $50\% \leq C < 70\%$ Skin Irrit. 2; H315: $35\% \leq C < 50\%$ Eye Dam. 1; H318: $C \geq 8\%$ Eye Irrit. 2; H319: $5\% \leq C < 8\%$ STOT SE 3; H335: $C \geq 35\%$	>1-<7%
CAS: 1310-58-3 EINECS: 215-181-3	Potassium Hydroxide ⚠ Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H302 Specific concentration limits: Skin Corr. 1A; H314: $C \geq 5\%$ Skin Corr. 1B; H314: $2\% \leq C < 5\%$ Skin Irrit. 2; H315: $0.5\% \leq C < 2\%$ Eye Irrit. 2; H319: $0.5\% \leq C < 2\%$	>1-<10%
CAS: 7758-11-4 EINECS: 231-834-5	Dipotassium Phosphate ⚠ Acute Tox. 3, H331	>0.1-<5%
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	<1%

· **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:** In case of unconsciousness place patient stably in side position for transportation.
- **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 symptoms persist consult doctor.
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.

(Contd. on page 3)

Safety data sheet

according to UK REACH

Printing date 28.03.2025

Version number 1

Revision: 28.03.2025

Trade name: Opal™ by Opalescence™ Prefilled Whitening Trays Gentle

(Contd. of page 2)

- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** 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:** 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

- **Precautions for safe handling:** See product labeling.
- **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:** Keep container tightly sealed.
- **Specific end use(s)** No further relevant information available.

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

7722-84-1 Hydrogen Peroxide

WEL Short-term value: 2.8 mg/m³, 2 ppm
Long-term value: 1.4 mg/m³, 1 ppm

1310-58-3 Potassium 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.

(Contd. on page 4)

Safety data sheet according to UK REACH

Printing date 28.03.2025

Version number 1

Revision: 28.03.2025

Trade name: Opal™ by Opalescence™ Prefilled Whitening Trays Gentle

(Contd. of page 3)

- **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 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 | Solid |
| · Colour: | White Opaque |
| · Odour: | Mint |
| · Odour threshold: | Not determined. |
| · Melting point/freezing point: | Undetermined. |
| · Boiling point or initial boiling point and boiling range | Undetermined. |
| · Flammability | Not determined. |
| · Lower and upper explosion limit | |
| · Lower: | Not determined. |
| · Upper: | Not determined. |
| · Flash point: | Not applicable. |
| · Decomposition temperature: | Not determined. |
| · pH at 20 °C | 5-7 |
| · Viscosity: | |
| · Kinematic viscosity | Not applicable. |
| · Dynamic: | Not applicable. |

(Contd. on page 5)

Safety data sheet according to UK REACH

Printing date 28.03.2025

Version number 1

Revision: 28.03.2025

Trade name: Opal™ by Opalescence™ Prefilled Whitening Trays Gentle

(Contd. of page 4)

· Solubility	
· water:	Partly miscible.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not applicable.
· Density and/or relative density	
· Density at 20 °C:	1.3 g/cm ³
· Relative density	Not determined.
· Vapour density	Not applicable.

· 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 applicable.

· 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** 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.

GB

(Contd. on page 6)

Safety data sheet according to UK REACH

Printing date 28.03.2025

Version number 1

Revision: 28.03.2025

Trade name: Opal™ by Opalescence™ Prefilled Whitening Trays Gentle

(Contd. of page 5)

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	4,265 mg/kg
Inhalative	LC50/4 h	>63.8 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)
Dermal	LC50 Fish	>5,000 mg/l (Fish)
	LD50	>21,900 mg/kg (rat)
Inhalative	LC50/4 h	10,000 mg/kg (rabbit)
		>0.1425 mg/l (rat)

7722-84-1 Hydrogen Peroxide

Oral	LC50 Fish	16.4 mg/l (Fish)
------	-----------	------------------

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)

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.
- **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)
------	--------------------------

(Contd. on page 7)

Safety data sheet according to UK REACH

Printing date 28.03.2025

Version number 1

Revision: 28.03.2025

Trade name: Opal™ by Opalescence™ Prefilled Whitening Trays Gentle

(Contd. of page 6)

7722-84-1 Hydrogen Peroxide

EC50	1.38 mg/l (Algae)
	2.4 mg/l (daphnia)

- **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 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.

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.*
- **Recommended cleansing agents:** *Water, if necessary together with cleansing agents.*

14 Transport information

- | | |
|--|------------------------|
| <ul style="list-style-type: none"> · UN number or ID number · ADR, IMDG, IATA | <i>not regulated</i> |
| <ul style="list-style-type: none"> · UN proper shipping name · ADR, ADN, IMDG, IATA | <i>not regulated</i> |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class | <i>not regulated</i> |
| <ul style="list-style-type: none"> · Packing group · ADR, IMDG, IATA | <i>not regulated</i> |
| <ul style="list-style-type: none"> · Environmental hazards: | <i>Not applicable.</i> |
| <ul style="list-style-type: none"> · Special precautions for user | <i>Not Applicable</i> |
| <ul style="list-style-type: none"> · Maritime transport in bulk according to IMO instruments | <i>Not applicable.</i> |
| <ul style="list-style-type: none"> · UN "Model Regulation": | <i>not regulated</i> |

GB

(Contd. on page 8)

Safety data sheet

according to UK REACH

Printing date 28.03.2025

Version number 1

Revision: 28.03.2025

Trade name: Opal™ by Opalescence™ Prefilled Whitening Trays Gentle

(Contd. of page 7)

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**

7722-84-1	Hydrogen Peroxide	12%
-----------	-------------------	-----

· **Regulated poisons**

None of the ingredients is listed.

· **Reportable explosives precursors**

None of the ingredients is listed.

· **Reportable poisons**

1310-58-3	Potassium Hydroxide	17% of total caustic alkalinity
-----------	---------------------	---------------------------------

· **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 oxidiser.

H272 May intensify fire; oxidiser.

H302 Harmful if swallowed.

H304 May be fatal if swallowed and enters airways.

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.

H331 Toxic if inhaled.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H411 Toxic to aquatic life with long lasting effects.

· **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

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

(Contd. on page 9)

Safety data sheet
according to UK REACH

Printing date 28.03.2025

Version number 1

Revision: 28.03.2025

Trade name: Opal™ by Opalescence™ Prefilled Whitening Trays Gentle

(Contd. of page 8)

ATE: Acute toxicity estimate values

Ox. Liq. 1: Oxidizing liquids – Category 1

Acute Tox. 4: Acute toxicity – Category 4

Acute Tox. 3: Acute toxicity – Category 3

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

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

· *** Data compared to the previous version altered.**

GB