Safety Data Sheet
according to WHS Regulations

Date of issue: 25.03.2025 Revision: 25.03.2025

1 Identification

· **Other means of identification**

· **Trade name: Opalescence™ Office Activator**

· **Article number:** SDS 349-001.05R01, 71195
· **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Bleaching Gel, Part 2 of 2
· **Application of the substance / the mixture** Professional Dental Bleaching Gel, Part 2 of 2

· **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

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:**
During normal opening times: +1 (801) 553-4862
CHEMTREC (NORTH AMERICA) : +1 (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) Identification

· **Classification of the substance or mixture**

Skin corrosion/irritation – Category 2 H315 Causes skin irritation.
Eye damage/irritation – Category 2A H319 Causes serious eye irritation.

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** GHS07
· **Signal word** Warning
· **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
· **Precautionary statements**
P264 Wash thoroughly after handling.
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.

(Contd. on page 2)

Safety Data Sheet
according to WHS Regulations

Date of issue: 25.03.2025 Revision: 25.03.2025

Trade name: Opalescence™ Office Activator

(Contd. of page 1)

P362+P364 Take off contaminated clothing and wash it before reuse.
P337+P313 If eye irritation persists: Get medical advice/attention.

3 Composition and Information on Ingredients

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

· **Dangerous components:**

56-81-5	Glycerin Eye damage/irritation – Category 2A, H319	<95%
7757-79-1	Potassium Nitrate Oxidising solids - Category 2, H272; Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Specific target organ toxicity (single exposure) – Category 3, H335-H336	<4%
1310-73-2	Sodium Hydroxide Acute toxicity - oral – Category 3, H301; Skin corrosion/irritation – Category 1A, H314; Eye damage/irritation – Category 1, H318; Acute toxicity - dermal – Category 4, H312	<3%

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

4 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 not possible.
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.
· **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:**
Water spray
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).

(Contd. on page 3)

Safety Data Sheet
according to WHS Regulations

Date of issue: 25.03.2025 Revision: 25.03.2025

Trade name: Opalescence™ Office Activator

(Contd. of page 2)

· **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.
· **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, Part 2 of 2

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
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 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.

(Contd. on page 4)

Safety Data Sheet
according to WHS Regulations

Date of issue: 25.03.2025 Revision: 25.03.2025

Trade name: Opalescence™ Office Activator

(Contd. of page 3)

· **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

9 Physical and Chemical Properties

· **General Information**	
· **Appearance:**	
· **Form:**	Gel
· **Colour:**	Dark red
· **Odour:**	Odourless
· **Odour threshold:**	Not determined.
· **pH-value at 20 °C:**	>12
· **Change in condition**	
· **Melting point/freezing point:**	Undetermined.
· **Initial boiling point and boiling range:**	Undetermined.
· **Flash point:**	Not applicable.
· **Flammability**	Not applicable.
· **Decomposition temperature:**	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:**	1.3 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.

(Contd. on page 5)

Safety Data Sheet
according to WHS Regulations

Date of issue: 25.03.2025 Revision: 25.03.2025

Trade name: Opalescence™ Office Activator

(Contd. of page 4)

· **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** Based on available data, the classification criteria are not met.

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

ATE (Acute Toxicity Estimates)

Oral	LD50	4,815-12,593 mg/kg (rat)
Dermal	LD50	50,000 mg/kg (rabbit)

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)

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)

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)

· **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.
· **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.

(Contd. on page 6)

Safety Data Sheet
according to WHS Regulations

Date of issue: 25.03.2025 Revision: 25.03.2025

Trade name: Opalescence™ Office Activator

(Contd. of page 5)

12 Ecological Information

· **Toxicity**

· **Aquatic toxicity:**	
56-81-5 Glycerin	
EC50	>10,000 mg/kg (Bacteria)
1310-73-2 Sodium Hydroxide	
EC50	40.38 mg/kg (Water Flea)

· **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.
Rinse off of bigger amounts into drains or the aquatic environment may lead to increased pH-values. A high pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably reduced, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.
· **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.

14 Transport information

· **UN-Number**	
· **ADG, IMDG, IATA**	UN1760
· **UN proper shipping name**	
· **ADG**	1760 CORROSIVE LIQUID, N.O.S. (Sodium Hydroxide)
· **IMDG, IATA**	CORROSIVE LIQUID, N.O.S. (Sodium Hydroxide)

· **Transport hazard class(es)**

· **ADG, IMDG, IATA**

· **Class** 8 Corrosive substances.

(Contd. on page 7)

Safety Data Sheet
according to WHS Regulations

Date of issue: 25.03.2025 Revision: 25.03.2025

Trade name: Opalescence™ Office Activator

(Contd. of page 6)

· **Label**	8
· **Packing group** · **ADG, IMDG, IATA**	III
· **Environmental hazards:**	Not applicable.
· **Special precautions for user** · **EMS Number:**	Warning: Corrosive substances. F-A,S-B
· **Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **Transport/Additional information:**	
· **ADG** · **Limited quantities (LQ)** · **Excepted quantities (EQ)**	5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **UN "Model Regulation":**	UN 1760 CORROSIVE LIQUID, N.O.S. (SODIUM HYDROXIDE), 8, III

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.

· **Australian Inventory of Industrial Chemicals**

All ingredients are listed.

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **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**
H272 May intensify fire; oxidizer.
H301 Toxic if swallowed.
H312 Harmful in contact with skin.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H318 Causes serious eye damage.

(Contd. on page 8)

Safety Data Sheet
according to WHS Regulations

Date of issue: 25.03.2025 Revision: 25.03.2025

Trade name: Opalescence™ Office Activator

(Contd. of page 7)

H319 Causes serious eye irritation.
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
NIOSH: National Institute for Occupational Safety
Oxidising solids - Category 2: Oxidizing solids – Category 2
Acute toxicity - oral – Category 3: Acute toxicity – Category 3
Acute toxicity - dermal – Category 4: Acute toxicity – Category 4
Skin corrosion/irritation – Category 1A: Skin corrosion/irritation – Category 1A
Skin corrosion/irritation – Category 2: Skin corrosion/irritation – Category 2
Eye damage/irritation – Category 1: Serious eye damage/eye irritation – Category 1
Eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A
Specific target organ toxicity (single exposure) – Category 3: Specific target organ toxicity (single exposure) – Category 3