

1 Identification
<ul style="list-style-type: none">· Other means of identification
<ul style="list-style-type: none">· Trade name: <u>Invisalign Professional Whitening System Powered by Opalescence™ PF 10% Mint</u>
<ul style="list-style-type: none">· Article number: SDS 14-120.03R01, 13509, 14543, 5420-AU, 5420-EU, 5420-U, 5420-US, 5436-U, 5436-US
<ul style="list-style-type: none">· Relevant identified uses of the substance or mixture and uses advised against Professional Dental Teeth Whitening Gel Not applicable
<ul style="list-style-type: none">· Application of the substance / the mixture Professional Dental Teeth Whitening Gel
<ul style="list-style-type: none">· Details of the supplier of the safety data sheet
<ul style="list-style-type: none">· Manufacturer/Supplier: Align Technology, Inc. 410 North Scottsdale Road Suite 1300 Tempe, Arizona 85288 USA Telephone: 602-742-2000
<ul style="list-style-type: none">· Further information obtainable from: Customer Service
<ul style="list-style-type: none">· Emergency telephone number: CHEMTREC (NORTH AMERICA) : +1 (800) 424-9300 (INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) Identification
<ul style="list-style-type: none">· Classification of the substance or mixture

<p>Acute toxicity - inhalation – Category 4 H332 Harmful if inhaled. Skin corrosion/irritation – Category 2 H315 Causes skin irritation. Eye damage/irritation – Category 2A H319 Causes serious eye irritation.</p>
<ul style="list-style-type: none">· Label elements· GHS label elements Void· Hazard pictograms GHS07· Signal word Warning· Hazard statements H332 Harmful if inhaled. 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. P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P280 Wear protective gloves / eye protection / face protection. P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312 Call a POISON CENTER/doctor if you feel unwell. P321 Specific treatment (see on this label).

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3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**

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

- **Dangerous components:**

56-81-5	Glycerin	$\geq 25\text{-}<50\%$
	⚠ Eye damage/irritation – Category 2A, H319	
124-43-6	Carbamide Peroxide	$>10\text{-}\leq 20\%$
	⚠ Oxidising solids - Category 3, H272; ⚠ Skin corrosion/irritation – Category 1B, H314; Eye damage/irritation – Category 1, H318	
1310-73-2	Sodium Hydroxide	$\geq 1\text{-}<3\%$
	⚠ Acute toxicity - oral – Category 3, H301; ⚠ Skin corrosion/irritation – Category 1A, H314; Eye damage/irritation – Category 1, H318; ⚠ Acute toxicity - dermal – Category 4, H312	
8006-90-4	Oils, Peppermint	$\geq 0.1\text{-}<1\%$
	⚠ Aspiration hazard – Category 1, H304; ⚠ Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Skin sensitisation – Category 1, H317; Flammable liquids – Category 4, H227	

- **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.

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.

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

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. If symptoms persist, consult a doctor.

- **After swallowing:** If swallowed in large quantities seek medical attention.

- **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:**

Wear fully protective suit.

Mouth respiratory protective device.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures:** Not required.

- **Environmental precautions:**

Dilute with plenty of water.

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).

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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.

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: 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 Teeth Whitening Gel

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/m ³
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WES	Long-term value: 10 mg/m ³ inhalable dust
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1310-73-2 Sodium Hydroxide

WES	Peak limitation: 2 mg/m ³
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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:

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.

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

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9 Physical and Chemical Properties

· General Information

· Appearance:

· Form:	Gel
· Colour:	Colourless
· Odour:	Product specific
· Odour threshold:	Not determined.
· pH-value at 20 °C:	5.3-7.5
· 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:	Not determined.
· 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 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 Alkalies
Metals

· Hazardous decomposition products: No dangerous decomposition products known.

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11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Harmful if inhaled.

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

ATE (Acute Toxicity Estimates)		
Oral	LD50	4,483-11,724 mg/kg
Dermal	LD50	46,552 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)
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)
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.
- **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 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 2 (German Regulation) (Self-assessment): hazardous for water

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Do not allow product to reach ground water, water course or sewage system.

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

Disposal should be in accordance with applicable regional, national and local laws and regulations.

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

· UN-Number	
· ADG, IMDG, IATA	not regulated
· UN proper shipping name	
· ADG, ADN, IMDG, IATA	not regulated
· Transport hazard class(es)	
· ADG, ADN, IMDG, IATA	not regulated
· 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 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

· 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

124-43-6 Carbamide Peroxide

S5, S6, S10

· 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.

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· Chemical safety assessment:

The 10-16% products meet 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

H227 Combustible liquid.

H272 May intensify fire; oxidizer.

H301 Toxic if swallowed.

H304 May be fatal if swallowed and enters airways.

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.

· 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

Flammable liquids - Category 4: Flammable liquids - Category 4

Oxidising solids - Category 3: Oxidizing solids - Category 3

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 1B: Skin corrosion/irritation - Category 1B

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

Skin sensitisation - Category 1: Skin sensitisation - Category 1

Aspiration hazard - Category 1: Aspiration hazard - Category 1

* Data compared to the previous version altered.

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