

HAND SANITIZER- alcohol gel

Alpha Aromatics

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Lavender Hand Sanitizing Gel 62%

The hand sanitizer is manufactured using only the following ingredients:

Alcohol(Ethanol) 62% (v/v).

Sorbitol 0.6% (v/v).

Glycerin 0.6% (v/v).

PEG-27 copolymer 0.375% (v/v)

Triethanol 0.7% (v/v)

Sterile distilled water or boiled cold water

fragrance

Active Ingredient(s)

Alcohol 62% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- Place a dime sized amount in hand. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

purified water USP, PEG-27 copolymer, sorbitol, glycerin, triethanolamine, fragrance

Package Label - Principal Display Panel

55 gallons NDC: 75009-762-01

Drug Facts	
Active Ingredient[s]	Purpose
Alcohol 62% v/v	Antiseptic
Use[s]	
Hand Sanitizer to help reduce bacteria that potentially can cause disease.	
Warnings	
For external use only. Flammable. Keep away from heat or flame.	
Do not use <ul style="list-style-type: none">• on children less than 2 months of age• on open skin wounds	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none">• Place enough product on hands to cover all surfaces. Rub hands together until dry.• Supervise children under 6 years of age when using this product to avoid swallowing	
Other information	
<ul style="list-style-type: none">• Store between 15-30C (59-86F).• Avoid freezing and excessive heat above 40C (104F).	
Inactive ingredients purified water USP, PEG-27 copolymer, sorbitol, glycerin, triethanolamine, fragrance	



GHS HAZARDS: Highly flammable liquid and vapor. May cause cancer.



DANGER

PRECAUTIONS: Obtain special instructions before use. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Wear protective gloves/eye protection/face protection.

FIRST AID: If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If exposed or concerned: Get medical advice attention. In case of fire: use sand, carbon dioxide or powder extinguisher to extinguish.

STORAGE: Store in a well-ventilated place. Keep cool.

DISPOSAL: Dispose of contents/container to industrial combustion plant.

**KEEP OUT OF REACH OF CHILDREN
CONSULT THE SDS
FOR FURTHER INFORMATION**

 **AIR-SCENT**
INTERNATIONAL
290 Alpha Drive | RIDC Industrial Park
Pittsburgh, PA 15238 USA
www.airscents.com

**62% Alcohol
Antiseptic Topical Gel
Hand Sanitizer**

55 Gallons / 208.19 liters

Non-Sterile Solution

©2020 ASI

275 gallons NDC: 75009-762-02

Drug Facts	
Active Ingredient[s]	Purpose
Alcohol 62% v/v	Antiseptic
Use[s]	
Hand Sanitizer to help reduce bacteria that potentially can cause disease.	
Warnings	
For external use only. Flammable. Keep away from heat or flame.	
Do not use <ul style="list-style-type: none">• on children less than 2 months of age• on open skin wounds	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none">• Place enough product on hands to cover all surfaces. Rub hands together until dry.• Supervise children under 6 years of age when using this product to avoid swallowing	
Other information	
<ul style="list-style-type: none">• Store between 15-30C (59-86F).• Avoid freezing and excessive heat above 40C (104F).	
Inactive ingredients purified water USP, PEG-27 copolymer, sorbitol, glycerin, triethanolamine, fragrance	



GHS HAZARDS: Highly flammable liquid and vapor. May cause cancer.



DANGER

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STORAGE: Store in a well-ventilated place. Keep cool.

DISPOSAL: Dispose of contents/container to industrial combustion plant.

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 **AIR-SCENT**
INTERNATIONAL
290 Alpha Drive | RIDC Industrial Park
Pittsburgh, PA 15238 USA
www.airscents.com

**62% Alcohol
Antiseptic Topical Gel
Hand Sanitizer**

275 Gallons / 1,040.98 liters

Non-Sterile Solution

©2020 ASI

5 gallons NDC: 75009-762-03

Drug Facts	
Active Ingredient[s]	Purpose
Alcohol 62% v/v	Antiseptic
Use[s]	
Hand Sanitizer to help reduce bacteria that potentially can cause disease.	
Warnings	
For external use only. Flammable. Keep away from heat or flame.	
Do not use	
<ul style="list-style-type: none"> on children less than 2 months of age on open skin wounds 	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years of age when using this product to avoid swallowing 	
Other information	
<ul style="list-style-type: none"> Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F). 	
Inactive ingredients purified water USP, PEG-27 copolymer, sorbitol, glycerin, triethanolamine, fragrance	



GHS HAZARDS: Highly flammable liquid and vapor. May cause cancer.



PRECAUTIONS: Obtain special instructions before use. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Wear protective gloves/eye protection/face protection.

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STORAGE: Store in a well-ventilated place. Keep cool.

DISPOSAL: Dispose of contents/container to industrial combustion plant.

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AIR-SCENT
INTERNATIONAL
290 Alpha Drive | RIDC Industrial Park
Pittsburgh, PA 15238 USA
www.airscents.com

**62% Alcohol
Antiseptic Topical Gel
Hand Sanitizer**

5 Gallons / 18.92 liters

Non-Sterile Solution

©2020 ASI

1 gallon NDC: 75009-762-04

Drug Facts	
Active Ingredient[s]	Purpose
Alcohol 62% v/v	Antiseptic
Use[s]	
Hand Sanitizer to help reduce bacteria that potentially can cause disease.	
Warnings	
For external use only. Flammable. Keep away from heat or flame.	
Do not use	
<ul style="list-style-type: none"> on children less than 2 months of age on open skin wounds 	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years of age when using this product to avoid swallowing 	
Other information	
<ul style="list-style-type: none"> Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F). 	
Inactive ingredients purified water USP, PEG-27 copolymer, sorbitol, glycerin, triethanolamine, fragrance	



GHS HAZARDS: Highly flammable liquid and vapor. May cause cancer.



PRECAUTIONS: Obtain special instructions before use. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Wear protective gloves/eye protection/face protection.

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STORAGE: Store in a well-ventilated place. Keep cool.

DISPOSAL: Dispose of contents/container to industrial combustion plant.

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AIR-SCENT
INTERNATIONAL
290 Alpha Drive | RIDC Industrial Park
Pittsburgh, PA 15238 USA
www.airscents.com

**62% Alcohol
Antiseptic Topical Gel
Hand Sanitizer**

1 Gallon / 3.78 liters

Non-Sterile Solution

©2020 ASI

1 quart NDC: 75009-762-05

Drug Facts	
Active Ingredient[s] Alcohol 62% v/v	Purpose Antiseptic
Use[s] Hand Sanitizer to help reduce bacteria that potentially can cause disease.	
Warnings For external use only. Flammable. Keep away from heat or flame.	
Do not use <ul style="list-style-type: none"> on children less than 2 months of age on open skin wounds 	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions <ul style="list-style-type: none"> Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years of age when using this product to avoid swallowing 	
Other information <ul style="list-style-type: none"> Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F). 	
Inactive ingredients purified water USP, PEG-27 copolymer, sorbitol, glycerin, triethanolamine, fragrance	



GHS HAZARDS: Highly flammable liquid and vapor. May cause cancer.



ANGER



PRECAUTIONS: Obtain special instructions before use. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Wear protective gloves/eye protection/face protection.

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STORAGE: Store in a well-ventilated place. Keep cool.

DISPOSAL: Dispose of contents/container to industrial combustion plant.

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290 Alpha Drive | RIDC Industrial Park
Pittsburgh, PA 15238 USA
www.airscents.com

62% Alcohol Antiseptic Topical Gel Hand Sanitizer

1 Quart / .946 liters

Non-Sterile Solution

©2020 ASI

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75009-762
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
LINALOOL, (+/-)- (UNII: D81QY6I88E)	0.05 mL in 100 mL
4-TERT-BUTYLCYCLOHEXYL ACETATE (UNII: 21EUM2B8UC)	0.01 mL in 100 mL
LINALYL ACETATE (UNII: 5K47SSQ51G)	0.07 mL in 100 mL
ACRYLIC ACID/ISOPHORONE DIISOCYANATE/PEG-27 COPOLYMER (UNII: R0R8I3X29J)	0.375 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.7 mL in 100 mL
DIHYDROMYRCENOL (UNII: 46L1B02ND9)	0.02 mL in 100 mL
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	0.02 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.6 mL in 100 mL
SORBITOL SOLUTION (UNII: 8KW3E207O2)	0.6 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	0.03 mL in 100 mL
PIPERONAL (UNII: KE109YAK00)	0.005 mL in 100 mL
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	0.005 mL in 100 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75009-762-01	208190 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75009-762-02	1040980 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75009-762-03	18920 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75009-762-04	3780 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75009-762-05	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	03/30/2020	

Labeler - Alpha Aromatics (041723545)

Establishment			
Name	Address	ID/FEI	Business Operations
Alpha Aromatics		041723545	manufacture(75009-762)

Revised: 5/2020

Alpha Aromatics