

HAND SANITIZER- alcohol liquid

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.

Hand Sanitizer 62%

This is a hand sanitizer manufactured with:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (62%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

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. For use when soap and water are not available.

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 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

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

55 gallons NDC: 75009-062-01

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 	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	



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



PRECAUTIONS: Obtain special instructions before use. Keep away from open flames/hot surfaces. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Do not eat, drink or smoke when using this product. Wear protective gloves/eye protection.

FIRST AID: If swallowed: Call a poison center/doctor if you feel unwell.

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

DISPOSAL: Dispose of contents/container in accordance with local regulations.

KEEP OUT OF REACH OF CHILDREN

CONSULT THE SDS FOR FURTHER INFORMATION

Manufactured by:
ALPHA AROMATICS
 290 Alpha Drive
 Pittsburgh, PA 15238
 www.alphaaromatics.com

62% Alcohol Hand Sanitizer Topical Solution
 55 Gallons / 208.19 liters

Antiseptic Hand Rub Non-Sterile Solution

©2020 AA

275 gallons NDC: 75009-062-02

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	
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When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.	
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FIRST AID: If swallowed: Call a poison center/doctor if you feel unwell.

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

DISPOSAL: Dispose of contents/container in accordance with local regulations.

KEEP OUT OF REACH OF CHILDREN

CONSULT THE SDS FOR FURTHER INFORMATION

Manufactured by:
ALPHA AROMATICS
 290 Alpha Drive
 Pittsburgh, PA 15238
 www.alphaaromatics.com

62% Alcohol Hand Sanitizer Topical Solution
 275 Gallons / 1,040.98 liters

Antiseptic Hand Rub Non-Sterile Solution

©2020 AA

5 gallons NDC: 75009-062-03

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

DISPOSAL: Dispose of contents/container in accordance with local regulations.

KEEP OUT OF REACH OF CHILDREN

CONSULT THE SDS FOR FURTHER INFORMATION

Manufactured by:
ALPHA AROMATICS
290 Alpha Drive
Pittsburgh, PA 15238
www.alphaaromatics.com

62% Alcohol Hand Sanitizer Topical Solution
5 Gallons / 18.92 liters

Antiseptic Hand Rub Non-Sterile Solution

©2020 AA

1 gallon NDC: 75009-062-04

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 	
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Directions	
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GHS HAZARDS: Highly flammable liquid and vapor. Harmful if swallowed. May cause cancer.



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FIRST AID: If swallowed: Call a poison center/doctor if you feel unwell.

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

DISPOSAL: Dispose of contents/container in accordance with local regulations.

KEEP OUT OF REACH OF CHILDREN

CONSULT THE SDS FOR FURTHER INFORMATION

Manufactured by:
ALPHA AROMATICS
290 Alpha Drive
Pittsburgh, PA 15238
www.alphaaromatics.com

62% Alcohol Hand Sanitizer Topical Solution
1 Gallon / 3.78 liters

Antiseptic Hand Rub Non-Sterile Solution

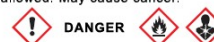
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1 quart NDC: 75009-062-05

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 • on children less than 2 months of age • on open skin wounds	
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Other Information • Store between 15-30C (59-86F). • Avoid freezing and excessive heat above 40C (104F).	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	



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

DISPOSAL: Dispose of contents/container in accordance with local regulations.

KEEP OUT OF REACH OF CHILDREN

CONSULT THE SDS FOR FURTHER INFORMATION

Manufactured by:
ALPHA AROMATICS
290 Alpha Drive
Pittsburgh, PA 15238
www.alphaaromatics.com

**62% Alcohol
Hand Sanitizer
Topical Solution**
1 Quart / .946 liters

**Antiseptic Hand Rub
Non-Sterile Solution**

©2020 AA

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75009-062
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75009-062-01	228079.07 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75009-062-02	975671.57 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75009-062-03	18920 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75009-062-04	3780 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
	NDC:75009-062-05			

5	NDC:75009-062-05	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(75009-062)

Revised: 5/2020

Alpha Aromatics