

## **ARCTIC CLEAN HAND SANITIZER- alcohol gel**

**Froggy's Fog LLC**

*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.*

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This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, 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 80% 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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away.

### 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

### Arctic Clean Hand Sanitizer

**8 FL OZ (236 mL)**

Drug Facts	
<b>ACTIVE INGREDIENTS</b> Ethyl Alcohol 62% v/v	<b>PURPOSE</b> Antiseptic
<b>USES</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>WARNINGS</b> For external use only. Flammable. Keep away from heat or flame.	
Do not use <ul style="list-style-type: none"><li>• on children less than 2 months of age</li><li>• on open skin wounds</li></ul>	
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 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.	
<b>DIRECTIONS</b> <ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul>	
<b>OTHER INFORMATION</b> <ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>	
<b>INACTIVE INGREDIENTS</b> acrylate polymer, aminomethyl propanol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

Manufactured by Froggy's Fog  
302 Rutherford Ln.  
Columbia, TN 38401

Distributed by:  
Manulife Freight and Logistics Corporation  
7901 4th St N, STE 300  
St. Petersburg, FL 33702

NDC: 75682-224-08

8 40472 11773 4

236 mL NDC: 75682-224-08

## ARCTIC CLEAN HAND SANITIZER

alcohol gel

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:75682-224

<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	RAPIDGEL EZ1 (UNII: 33JH4A7R2K)			
	LEMON OIL (UNII: I9GRO824LL)			
	GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL		
	HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		
	WATER (UNII: 059QF0KO0R)			
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:75682-224-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
<b>Marketing Information</b>				
	<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
	OTC monograph not final	part333A	03/30/2020	

**Labeler** - Froggy's Fog LLC (144348161)

**Registrant** - Froggy's Fog LLC (144348161)

<b>Establishment</b>				
	<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
	Froggy's Fog LLC		144348161	manufacture(75682-224)