

## **SANTATIZER HAND GEL- 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.

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

- 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

### SANTatizer Hand Gel



59.14 mL NDC: 75682-464-02

**Naughty List**

- X Germs
- X Bacteria
- X Viruses

**SANTatizer®**

**62% Alcohol Antiseptic  
HAND SANITIZER GEL**  
Topical Solution of Non-Sterile Solution

**? Candy Cane Scent ?**

**4 FL OZ (118.294mL)**

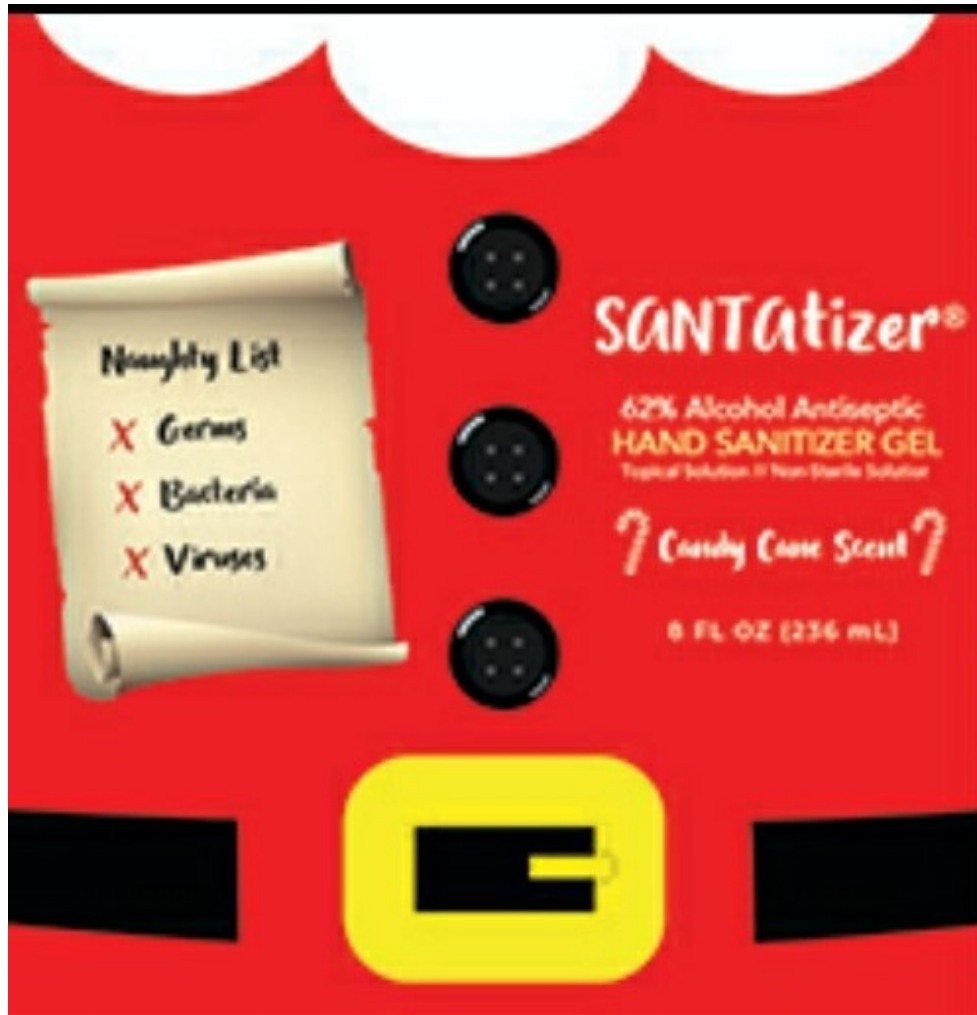
**Drug Facts**

ACTIVE INGREDIENTS	PURPOSE
62% Alcohol (62% v/v)	Antiseptic
<b>Uses</b>	
Useful sanitizes 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.	
<b>To use</b>	
It is advised for use by 2 months of age or in open skin wounds.	
<b>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, flush eyes thoroughly with water.</b>	
<b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (800) 527-0899.</b>	
<b>Directions</b>	
• Place enough product on hands to cover all surfaces. Rub hands together until dry.	
• <b>Caution: Children under 6 years of age when using this product to avoid suffocation.</b>	
<b>Other Ingredients</b>	
• Benzyl Alcohol, 1% - 10% (10-100%) • Benzyl Benzoate and benzyl alcohol • Benzyl Benzoate	
<b>Contains Ingredients</b>	
• Contains: Alcohol, benzyl alcohol, benzyl benzoate, fragrance, glycerin, hydroxyacetone, methylparaben, propylparaben, sodium benzoate, sodium hydroxide, water	

© 2011  
 3000 Northpark Drive, Columbia, SC 29910  
 803-799-8999  
 NDC: 75682-464-04

40472 11752

118.284 mL NDC: 75682-464-04



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>WARNING</b> For external use only. Flammable. Keep away from heat or flame.	
<b>DO NOT USE</b> • In children less than 2 months of age • In open skin wounds	
<b>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, flush eyes thoroughly with water.</b>	
<b>Stop use and ask doctor if:</b> • irritation or rash occurs. • There are 16 signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center for advice.	
<b>PRECAUTIONS</b> • Place enough product on hands to cover all surfaces. Rub hands together until dry.	
• Supervise children under 9 years of age when using this product to avoid swallowing.	
<b>STORAGE AND HANDLING</b> • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 30°C (86°F)	
<b>ACTIVE INGREDIENTS</b> ethylene glycol, antiseptic preservative, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water v/v	

Shipping to  
 302 Netherland Ave., Columbia, TN 38401  
 615-868-8888  
 NDC 75682-464-08  
  
 8 40472 11753 6

236 mL NDC: 75682-464-08





Drug Facts	
ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 62% v/v	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> <i>For external use only. Flammable. Keep away from heat or flame.</i>	
<b>Do not use</b> • 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.	
<b>Stop use and ask doctor if</b> irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>DIRECTIONS</b> • 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.	
<b>OTHER INFORMATION</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>INACTIVE INGREDIENTS</b> acrylate polymer, aminocethyl propandiol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

Froggy's Fog  
302 Rutherford Ln. Columbia, TN 38401  
615-469-4906  
NDC: 75682-464-16  
8 40472 11750 5

473.176 mL NDC: 75682-464-16



Drug Facts	
ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 62% v/v	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> <i>For external use only. Flammable. Keep away from heat or flame.</i>	
<b>Do not use</b> • 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.	
<b>Stop use and ask doctor if</b> irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>DIRECTIONS</b> • 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.	
<b>OTHER INFORMATION</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>INACTIVE INGREDIENTS</b> acrylate polymer, aminocethyl propandiol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

Froggy's Fog  
302 Rutherford Ln. Columbia, TN 38401  
615-469-4906  
NDC: 75682-464-32  
8 40472 11754 3

946.353 mL NDC: 75682-464-32



1892.71 mL NDC: 75682-464-64

Drug Facts	
ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 62% v/v	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>in 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	

Frogg's Fog  
 302 Rutherford Ln, Columbia, TN 38401  
 615-469-4906  
 NDC: 756827-464-64



**Naughty List**

- X Germs
- X Bacteria
- X Viruses

**SANTatizer®**

**62% Alcohol Antiseptic  
HAND SANITIZER GEL**  
Topical Solution // Non-Sterile Solution

**Candy Cane Scent**

1 Liter (1000 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> <i>For external use only. Flammable. Keep away from heat or flame.</i>	
<b>Do not use</b> • 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.	
<b>Stop use and ask doctor if irritation or rash occurs.</b> These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>DIRECTIONS</b> • 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.	
<b>OTHER INFORMATION</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>INACTIVE INGREDIENTS</b> acrylate polymer, aminoethyl propanol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

Frogg's Fog  
302 Rutherford Ln, Columbia, TN 38401  
615-469-4906  
NDC: 75682-464-33

8 40472 11757 4

1000 mL NDC: 75682-464-33





Drug Facts	
ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 62% v/v	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>• in 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 8 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	

Frogg's Fog  
302 Rutherford Ln, Columbia, TN 38401  
615-469-4906  
NDC: 75682-464-67



8 40472 11758 1

2000 mL NDC: 75682-464-67



Drug Facts	
ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 62% v/v	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>• in 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 8 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	

Frogg's Fog  
302 Rutherford Ln, Columbia, TN 38401  
615-469-4906  
NDC: 75682-464-01



8 40472 11756 7



3785.412 mL NDC: 75682-464-01

**SANTATIZER HAND GEL**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75682-464
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	
RAPIDGEL EZ1 (UNII: 33JH4A7R2K)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75682-464-01	3785.412 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75682-464-67	2000 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75682-464-33	1000 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75682-464-64	1892.71 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75682-464-32	946.353 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75682-464-16	472.176 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75682-464-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
8	NDC:75682-464-04	118.284 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
9	NDC:75682-464-02	59.14 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

**Marketing Information**

<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)

**Establishment**

Name	Address	ID/FEI	Business Operations
Froggy's Fog LLC		144348161	manufacture(75682-464)

Revised: 10/2020

Froggy's Fog LLC