

SANTATIZER HAND SANITIZER 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.

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 Sanitizer Gel



59.14 mL NDC: 75682-849-02

Naughty List

- X Germs
- X Bacteria
- X Viruses

SANTatizer®

70% Alcohol Antiseptic HAND SANITIZER GEL
Typical Solution or Non-Sterile Solution

? Candy Cane Scent ?

4 FL OZ (118.294mL)

Drug Facts

ACTIVE INGREDIENTS	PURPOSE
70% Alcohol (70% v/v)	Antiseptic

Uses
 Used routinely 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
 if is within two (2) weeks of age
 if is open with residue

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (800) 527-0899.

Directions
 • Place enough product on hands to cover all surfaces. Rub hands together until dry.
 • Repeat if/when under 18 years of age when using this product to avoid suffocation.

Other Warnings
 • Store between 15-30°C (59-86°F).
 • Avoid freezing and excessive heat above 30°C (86°F).

Keep Out of Reach of Children
 Contains: Polymers, alcohol(yl) propyl, fragrance, glycerin, hydroxyethyl cellulose, polyethylene glycol, purified water, and hydroxyethyl cellulose.

Manufactured by:
 3M HealthCare, Columbia, SC 29615
 803.433.4000
 NDC: 75682-849-04

8 40472 11752 9

118.284 mL NDC: 75682-849-04



Drug Facts	
ACTIVE INGREDIENTS Ethyl Alcohol 70% v/v	PURPOSE Antiseptic
USES Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
WARNING For external use only. Flammable. Keep away from heat or flame.	
DO NOT USE • In children less than 2 months of age • In open skin wounds	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, flush eyes thoroughly with water.	
Stop use and ask doctor if: • irritation or rash occurs. • There are 16 signs of a serious condition.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center for advice.	
PRECAUTIONS • 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.	
STORAGE AND HANDLING • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 30°C (86°F)	
ACTIVE INGREDIENTS ethylene glycol, antiseptic preservative, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water v/v	

Shipping to
 302 Netherland Ave., Columbia, TN 38401
 615-882-8888
 NDC 75682-849-08

 8 40472 11753 6

236 mL NDC: 75682-849-08



Drug Facts	
ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 70% v/v	Antiseptic
USES Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
WARNINGS <i>For external use only. Flammable. Keep away from heat or flame.</i>	
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 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 8 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 acrylate polymer, aminomethyl propanol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

Froggy's Fog
302 Rutherford Ln, Columbia, TN 38401
615-469-4906
NDC: 75682-849-16



473.176 mL NDC: 75682-849-16



Drug Facts	
ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 70% v/v	Antiseptic
USES Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
WARNINGS <i>For external use only. Flammable. Keep away from heat or flame.</i>	
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 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 8 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 acrylate polymer, aminomethyl propanol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

Froggy's Fog
302 Rutherford Ln, Columbia, TN 38401
615-469-4906
NDC: 75682-849-32



946.353 mL NDC: 75682-849-32

Naughty List

- X Germs
- X Bacteria
- X Viruses

SANTatizer®

**70% Alcohol Antiseptic
HAND SANITIZER GEL**
Topical Solution // Non-Sterile Solution

Candy Cane Scent

64 FL OZ (1892.71 mL)

Drug Facts	
ACTIVE INGREDIENTS Ethyl Alcohol 70% v/v	PURPOSE Antiseptic
USES 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 <ul style="list-style-type: none">• 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 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 8 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 acrylate polymer, aminomethyl propanol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

Froggy's Fog
302 Rutherford Ln. Columbia, TN 38401
615-469-4906

NDC: 756827-849-64



1892.71 mL NDC: 75682-849-64



Drug Facts	
ACTIVE INGREDIENTS Ethyl Alcohol 70% v/v	PURPOSE Antiseptic
USES Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
WARNINGS <i>For external use only. Flammable. Keep away from heat or flame.</i>	
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 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 • <i>Place enough product on hands to cover all surfaces. Rub hands together until dry.</i> • <i>Supervise children under 8 years of age when using this product to avoid swallowing.</i>	
OTHER INFORMATION • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
INACTIVE INGREDIENTS acrylate polymer, aminoethyl propanol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

Froggy's Fog
302 Rutherford Ln. Columbia, TN 38401
615-469-4906

NDC: 75682-849-33



1000 mL NDC: 75682-849-33



Drug Facts

ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 70% v/v	Antiseptic

USES
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 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 8 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

acrylate polymer, antiseptic preservative, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP

Frogg's Fog
 302 Rutherford Ln, Columbia, TN 38401
 615-469-4906
 NDC: 75682-849-67



2000 mL NDC: 75682-849-67



3785.412 mL NDC: 75682-849-01

SANTATIZER HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75682-849
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75682-849-01	3785.412 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75682-849-67	2000 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75682-849-33	1000 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75682-849-64	1892.71 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75682-849-32	946.353 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75682-849-16	473.176 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75682-849-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
8	NDC:75682-849-04	118.284 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
9	NDC:75682-849-02	59.14 mL in 1 BOTTLE, PLASTIC; 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 - Froggy's Fog LLC (144348161)**Registrant** - Froggy's Fog LLC (144348161)**Establishment**

Name	Address	ID/FEI	Business Operations
Froggy's Fog LLC		144348161	manufacture(75682-849)

Revised: 10/2020

Froggy's Fog LLC