

SIMPLY 62 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.

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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

Simply 62 Hand Sanitizer Gel

946352.946 mL NDC: 75682-332-25

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

250 US Gallons (946352.946 mL)

1892 mL NDC: 75682-332-64

Drug Facts	
ACTIVE INGREDIENTS Ethyl Alcohol 62% 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 <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 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 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: 75682-332-25



SIMPLY

62

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

64 FL OZ (1892 mL)

Drug Facts	
ACTIVE INGREDIENTS Ethyl Alcohol 62% 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 <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, aminoethyl propanol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

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

NDC: 75682-332-64



946 mL NDC: 75682-332-32

SIMPLY

62

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

32 FL OZ (946 mL)

Drug Facts	
ACTIVE INGREDIENTS Ethyl Alcohol 62% 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 <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, aminoethyl propanol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

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

NDC: 75682-332-32



473 mL NDC: 75682-332-16

SIMPLY

62

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

16 FL OZ (473 mL)

Drug Facts	
ACTIVE INGREDIENTS Ethyl Alcohol 62% w/v	PURPOSE Antiseptic
USE 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 <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 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 2 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 methyl paraben, antiseptic preservative, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

Frigger's Inc.
302 Rutherford Ln, Columbia, TN 38401
615-469-4906

NDC: 75682-332-16



236.588mL NDC: 75682-332-08

SIMPLY

62

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

8 FL OZ (236.588 mL)

Drug Facts	
ACTIVE INGREDIENTS Ethyl Alcohol 62% w/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. There 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.	
STORAGE/STABILITY <ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F)	
INACTIVE INGREDIENTS acrylate polymers, antiseptical preservative, fragrance, glycerol, hydrogen peroxide, polyethylene glycol, purified water USP	

Procter & Gamble
312 Rutherford Ln., Columbia, TN 38401
415-469-4904

NDC: 75682-332-08



118.294mL NDC: 75682-332-04

SIMPLY

62

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

4 FL OZ (118.294 mL)

Drug Facts	
ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 62% w/v	Antiseptic
Uses Wash hands to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings Do not use with flammable. Keep away from heat & 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. There may be signs of a allergic reaction.	
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 30C (86F)	
Contains acrylate polymers, aminomethyl propanol, fragrance, glycerin, hydrogen peroxide, propylthiouracil glycol purified water USP	

Therapy, Inc.
9210 Northpark Drive, Columbia, WI 53101
410-400-4990

NDC 75682-332-04



3785.412mL NDC: 75682-332-02

SIMPLY

62

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

1 US Gallon (3785.412 mL)

Drug Facts

ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 62% 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, aminocetyl propanol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP

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

NDC: 75682-332-02

8 40472 11728 4

SIMPLY

62

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

1 Liter (1000 mL)

Drug Facts	
ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 62% 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 <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 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	
acrylate polymer, aminocethyl propandl, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

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

NDC: 75682-332-62



1000 mL NDC: 75682-332-01

SIMPLY 62 HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75682-332
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: 059QF0K00R)	
RAPIDGEL EZ1 (UNII: 33JH4A7R2K)	
LEMON OIL (UNII: I9GRO824LL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75682-332-01	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75682-332-02	3785.412 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75682-332-04	118.294 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75682-332-08	236.588 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75682-332-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75682-332-32	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75682-332-64	1892 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
8	NDC:75682-332-25	946352.946 mL in 1 TANK; 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(75682-332)

Revised: 10/2020

Froggy's Fog LLC