

SMPLY SANITIZER LAVENDER- 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

SMPLY Sanitizer Lavender

Our Simple Story

SMPLY Sanitizer was created so you can live freely and live fully. From gas pumps to fist bumps, germs are everywhere, but they don't have to be on you.

With 70% alcohol content, we are ready for the future of worry-free high fives. Feel good. Feel confident. Live SEMPLY.

SMPLY.

SMPLY™
sanitizer

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

1 US Gallon (3785 mL)

We clean up well
together.

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 uses only. Flammable. Keep away from heat or flame.	
DO NOT USE • 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 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. • Avoid breathing and excessive heat above 40C (104F)	
OTHER INFORMATION • Store between 15-30C (59-86F). • Supervise children under 6 years of age when using this product to avoid swallowing.	
INACTIVE INGREDIENTS acrylate polymers, dimethyl propand, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

An Epic Essentials® Brand
502 Rutherford Ln, Columbia, TN 38401
615-469-4905
NDC: 75682-528-01

8 40472 11844 1

3785 mL NDC: 75682-528-01



Our Simple Story

SMPLY Sanitizer was created so you can live freely and live fully. From gas pumps to fist bumps, germs are everywhere, but they don't have to be on you.

With 70% alcohol content, we are ready for the future of worry-free high fives. Feel good. Feel confident. Live SMPLY.



SMPLY™

sanitizer



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

64 FL OZ (1893 mL)

We clean up well
together.

Drug Facts

ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 70% w/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 uses only. Flammable. Keep away from heat or flame.	
DO NOT USE - 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 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. - Avoid breathing and excessive heat above 40C (104F)	
OTHER INFORMATION - Store between 15-30C (59-86F). - Supervise children under 6 years of age when using this product to avoid swallowing.	
INACTIVE INGREDIENTS acrylate polymers, isoamyl alcohol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

An Epic Essentials™ Brand
302 Rutherford Ln, Columbia, TN 38401
615.469.4906
NDC: 75682-528-64



1893 mL NDC: 75682-528-64



Our Simple Story

SMPLY Sanitizer was created so you can live freely and live fully. From gas pumps to fist bumps, germs are everywhere, but they don't have to be on you.

With 70% alcohol content, we are ready for the future of worry-free high fives. Feel good. Feel confident. Live SMPLY.



SMPLY™

sanitizer



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

32 FL OZ (946 mL)

We clean up well
together.

Drug Facts

ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 70% w/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 uses only. Flammable. Keep away from heat or flame.	
DO NOT USE - 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 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. - Avoid breathing and excessive heat above 40C (104F)	
OTHER INFORMATION - Store between 15-30C (59-86F). - Supervise children under 6 years of age when using this product to avoid swallowing.	
INACTIVE INGREDIENTS acrylate polymers, isoamyl alcohol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

An Epic Essentials™ Brand
302 Rutherford Ln, Columbia, TN 38401
615.469.4906
NDC: 75682-528-32



946 mL NDC: 75682-528-32

Our Simple Story

SMPLY Sanitizer was created so you can live freely and live fully. From gas pumps to fist bumps, germs are everywhere, but they don't have to be on you.

With 70% alcohol content, we are ready for the future of worry-free high fives. Feel good. Feel confident. Live SMPLY.



SMPLY™ sanitizer



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

16 FL OZ (473 ml)

We clean up well
together.

Drug Facts

ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 70% v/v	Antiseptic
USE Hand sanitizer helps reduce bacteria that potentially can cause illness. For use when soap and water are not available.	
WARNINGS For external use only. Flammable. Keep away from heat or flame.	
PRECAUTIONS - Use in children less than 2 months of age - Use upon 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 - Place enough product on hands to cover all surfaces. Rub hands together until dry. - Avoid breathing and excessive heat above 40°C (104°F)	
STORAGE - Store between 10-30°C (50-86°F) - Supervise children under 6 years of age when using this product to avoid swallowing.	
OTHER INGREDIENTS acrylate polymer, ammonyl propyl, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

An Eptic Essentials® Brand
300 Rutherford LA, Columbia, TN 38401
615-469-4906
NDC 75682-528-16



473 mL NDC: 75682-528-16

Our Simple Story

SMPLY Sanitizer was created so you can live freely and live fully. From gas pumps to fist bumps, germs are everywhere, but they don't have to be on you.

With 70% alcohol content, we are ready for the future of worry-free high fives. Feel good. Feel confident. Live SMPLY.

WWW.SMPLYBRANDS.COM



SMPLY™ sanitizer



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

8 FL OZ (236 ml)

We clean up well
together.

Drug Facts

ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 70% v/v	Antiseptic
USE Hand sanitizer helps reduce bacterial pathogens that cause illness. For use when soap and water are not available.	
WARNINGS For external use only. Flammable. Keep away from heat or flame.	
PRECAUTIONS - Use in children less than 2 months of age - Use upon 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 - Place enough product on hands to cover all surfaces. Rub hands together until dry. - Avoid breathing and excessive heat above 40°C (104°F)	
STORAGE - Store between 10-30°C (50-86°F) - Supervise children under 6 years of age when using this product to avoid swallowing.	
OTHER INGREDIENTS acrylate polymer, ammonyl propyl, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

An Eptic Essentials® Brand
300 Rutherford LA, Columbia, TN 38401
615-469-4906 - NDC 75682-528-08



236 mL NDC: 75682-528-08

Our Simple Story

SMPLY Sanitizer was created so you can live freely and live fully. From gas pumps to fist bumps, germs are everywhere, but they don't have to be on you.

With 70% alcohol content, we are ready for the future of worry-free high fives. Feel good. Feel confident. Live SMPLY.



SMPLY[™]

sanitizer



Lavender Scented GEL HAND SANITIZER
70% Alcohol Antiseptic Topical Solution
Non-Sterile Solution

4 FL OZ (118 mL)

We clean up well together.

Drug Facts

ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 70% v/v	Antiseptic

USE
Hand sanitizer to help reduce germs that potentially can cause disease. For use after cough and cold season and outbreaks.

WARNING
For external use only. Flammable. Keep away from heat or flame.

PRECAUTIONS
- Do not use on children less than 2 months of age
- Do not open skin wounds

When using flammable hand sanitizer, avoid contact with 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 contact dermatitis.

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.
- Avoid breathing and excessive heat above 100°F (38°C).

OTHER INFORMATION
- Store between 15-30°C (59-86°F).
- Expiration date on bottom of cap when using this product to avoid spoilage.

INGREDIENTS
ethylene alcohol, ethyl alcohol, propylene glycol, perfume, glycerin, hydroxy-peroxide, polyethylene glycol, purified water USP

An Epic Essentials[™] Brand
302 Rutherford Ln, Columbia, TN 38401
675.460.4906
NDC: 75682-528-04



118 mL NDC: 75682-528-04

Our Simple Story

SMPLY Sanitizer was created so you can live freely and live fully. From gas pumps to fist bumps, germs are everywhere, but they don't have to be on you.

With 70% alcohol content, we are ready for the future of worry-free high fives. Feel good. Feel confident. Live SMPLY.



SMPLY[™]

sanitizer



Lavender Scented GEL HAND SANITIZER
70% Alcohol Antiseptic Topical Solution
Non-Sterile Solution

2 FL OZ (59 mL)

We clean up well together.

Drug Facts

ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 70% v/v	Antiseptic

USE
Hand sanitizer to help reduce germs that potentially can cause disease. For use after cough and cold season and outbreaks.

WARNING
For external use only. Flammable. Keep away from heat or flame.

PRECAUTIONS
- Do not use on children less than 2 months of age
- Do not open skin wounds

When using the product, avoid contact with 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 contact dermatitis.

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.
- Avoid breathing and excessive heat above 100°F (38°C).

OTHER INFORMATION
- Store between 15-30°C (59-86°F).
- Expiration date on bottom of cap when using this product to avoid spoilage.

INGREDIENTS
ethylene alcohol, ethyl alcohol, propylene glycol, perfume, glycerin, hydroxy-peroxide, polyethylene glycol, purified water USP

An Epic Essentials[™] Brand
302 Rutherford Ln, Columbia, TN 38401
675.460.4906
NDC: 75682-528-02



59 mL NDC: 75682-528-02

SMPLY SANITIZER LAVENDER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75682-528
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
FRAGRANCE LAVENDER ORC1800979 (UNII: 1B40MIN2W5)	
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75682-528-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75682-528-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75682-528-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75682-528-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75682-528-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75682-528-64	1893 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75682-528-01	3785 mL in 1 JUG; 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(75682-528)