

## **SMPLY 70 CITRUS LIQUID HAND SANITIZER- alcohol liquid**

### **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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## 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 70 Citrus Liquid Hand Sanitizer



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 SPLY.

**SMPLY**

**SMPLY™**  
sanitizer

Citrus Scented  
LIQUID HAND SANITIZER  
70% Alcohol Antiseptic  
Topical Solution  
Non-Sterile Solution

WWW. SPLYBRANDS.COM      2 FL OZ (59 mL)      We clean up well together.

Drug Facts	
<b>ACTIVE INGREDIENTS</b> Ethyl Alcohol 70% 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 uses only. Flammable. Keep away from heat or flame.	
<b>DO NOT USE</b> • on children less than 2 months of age • on open skin wounds	
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<b>Stop use and ask doctor</b> if 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. • Avoid freezing and excessive heat above 40C (104F)	
<b>OTHER INFORMATION</b> • Store between 15-30C (59-86F). • Supervise children under 6 years of age when using this product to avoid swallowing.	
<b>INACTIVE INGREDIENTS</b> acrylate polymer, aminoethyl propanol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

An Epic Essentials™ Brand  
Distributed by: SPLY.  
1536 N. Main St.,  
Mt. Pleasant, TN 38474  
615.393.6700 • NDC: 75682-100-02



8 40472 11859 5

59mL NDC: 75682-100-02



## 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.

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**SMPLY™**  
sanitizer

*Citrus Scented*  
**LIQUID HAND SANITIZER**  
70% Alcohol Antiseptic  
Topical Solution  
Non-Sterile Solution

4 FL OZ (118 ml)

We clean up well together.

ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 70% v/v	Antiseptic
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8 40472 11914 1

118mL NDC: 75682-100-04



## Our Simple Story

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**SMPLY™**  
sanitizer

*Citrus Scented*  
**LIQUID HAND SANITIZER**  
70% Alcohol Antiseptic  
Topical Solution  
Non-Sterile Solution

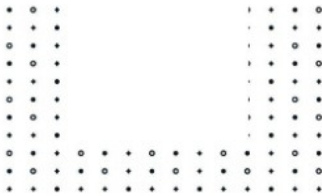
8 FL OZ (236 ml)

We clean up well together.

ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 70% v/v	Antiseptic
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8 40472 11915 8

236mL NDC: 75682-100-08



### 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.



Drug Facts	
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1536 N. Main St.  
Mt. Pleasant, TN 38474  
615.393.6700 • NDC: 75682-100-16



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16 FL OZ (473 ml)

We clean up well together.

473mL NDC: 75682-100-16



### Our Simple Story

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An Epic Essentials™ Brand  
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615.393.6700 • NDC: 75682-100-32



WWW.SMPYBRANDS.COM

32 FL OZ (946 ml)

We clean up well together.

946mL NDC: 75682-100-32





### Our Simple Story

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**SMPLY™**  
sanitizer

**Citrus Scented LIQUID HAND SANITIZER**  
70% Alcohol Antiseptic  
Topical Solution  
Non-Sterile Solution

WWW.SMPLYBRANDS.COM

64 FL OZ (1893 mL)

We clean up well together.

### Drug Facts

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An Epic Essentials™ Brand  
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615.393.6700 • NDC: 75682-100-64



1893mL NDC: 75682-100-64



### Our Simple Story

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sanitizer

**Citrus Scented LIQUID HAND SANITIZER**  
70% Alcohol Antiseptic  
Topical Solution  
Non-Sterile Solution

WWW.SMPLYBRANDS.COM

1 US Gallon (3785 mL)

We clean up well together.

### Drug Facts

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Ethyl Alcohol 70% v/v	Antiseptic
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615.393.6700 • NDC: 75682-100-01



3785mL NDC: 75682-100-01

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**SMPLY**

**SMPLY™ sanitizer**

**Citrus Scented LIQUID HAND SANITIZER**  
70% Alcohol Antiseptic Topical Solution  
Non-Sterile Solution

**WWW.SMPLYBRANDS.COM**      **55 Gallons (208198 mL)**      **We clean up well together.**

**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.

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**OTHER INFORMATION**  
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**INACTIVE INGREDIENTS**  
acrylate polymer, amineoethyl propanoate, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP

An Epic Essentials™ Brand  
Distributed by: SMPLY,  
1536 N. Main St.  
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615.393.6700 • NDC: 75682-100-55

8 40472 11920 2

208198mL NDC: 75682-100-55

**Our Simple Story**

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

**SMPLY**

**SMPLY™ sanitizer**

**Citrus Scented LIQUID HAND SANITIZER**  
70% Alcohol Antiseptic Topical Solution  
Non-Sterile Solution

**WWW.SMPLYBRANDS.COM**      **250 Gallons (946353 mL)**      **We clean up well together.**

**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.

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**INACTIVE INGREDIENTS**  
acrylate polymer, amineoethyl propanoate, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP

An Epic Essentials™ Brand  
Distributed by: SMPLY,  
1536 N. Main St.  
Mt. Pleasant, TN 38474  
615.393.6700 • NDC: 75682-100-25

8 40472 11921 9

946353 mL NDC: 75682-100-25

<b>SMPLY 70 CITRUS LIQUID HAND SANITIZER</b>			
alcohol liquid			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75682-100
<b>Route of Administration</b>	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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	
LEMON OIL (UNII: I9GRO824LL)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75682-100-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75682-100-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75682-100-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75682-100-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75682-100-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75682-100-64	1893 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75682-100-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
8	NDC:75682-100-55	208198 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
9	NDC:75682-100-25	946353 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(75682-100)

