

SMPLY ALOE HAND SANITIZER- 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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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 Aloe 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
GEL HAND SANITIZER
70% Alcohol Antiseptic
Topical Solution
Non-Sterile Solution

Drug Facts

ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 70% v/v	Antiseptic

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INACTIVE INGREDIENTS
acrylate polymer, amine ethyl propanol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP

An Epic Essentials™ Brand
Distributed by: SPLY,
1556 N. Main St.
Mt. Pleasant, TN 38474
615.393.6700 • NDC: 75682-775-64

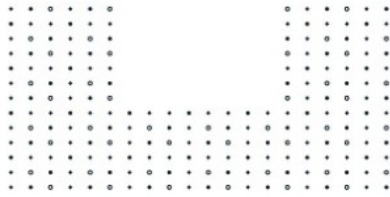
WWW.SMPYBRANDS.COM

64 FL OZ (1893 mL)

We clean up well together.

8 40472 11839 7

1893mL NDC: 75682-775-64



Our Simple Story

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1536 N. Main St.
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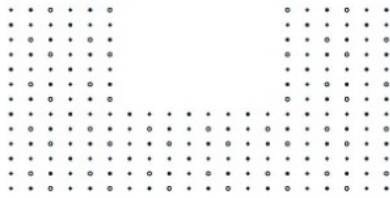


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55 Gallons (208198 mL)

We clean up well together.

208198mL NDC: 75682-775-55



Our Simple Story

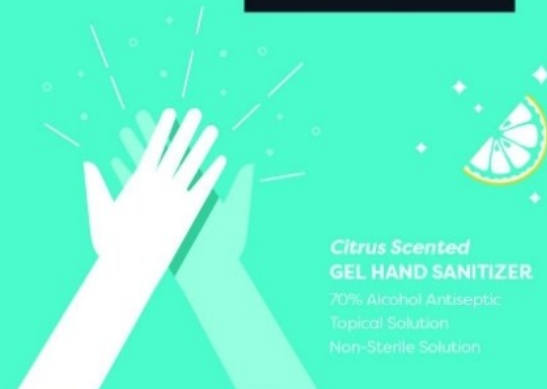
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Topical Solution
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An Epic Essentials™ Brand
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1536 N. Main St.
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615.395.6700 • NDC: 75682-775-25

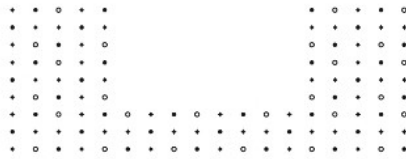


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250 Gallons (946353 mL)

We clean up well together.

946353mL NDC: 75682-775-25



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SPLY™
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8 FL OZ (236 ml)

We clean up well together.

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Ethyl Alcohol 70% v/v	Antiseptic
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Manufactured by Froggy's Fog
1536 N. Main St.
Mt. Pleasant, TN 38474
815.469.4906 - NDC: 75682-775-08

8 40472 11817 5

236 mL NDC: 75682-775-08



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4 FL OZ (118 ml)

We clean up well together.

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An Epic Essentials™ Brand
Manufactured by Froggy's Fog
1536 N. Main St.
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8 40472 11814 4

118 mL NDC: 75682-775-04

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SMPLY™

sanitizer



**Citrus Scented
GEL HAND SANITIZER**

70% Alcohol Antiseptic
Topical Solution
Non-Sterile Solution

Drug Facts

ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 70% v/v	Antiseptic
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An Epic Essentials™ Brand
Manufactured by: Froggy's Fog
1536 N. Main St.
Mt. Pleasant, TN 38474
615.469.4906 • NDC: 75682-775-32



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32 FL OZ (946 mL)

We clean up well
together.

946 mL NDC: 75682-775-32

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2 FL OZ (59 mL)

We clean up well
together.

59 mL NDC: 75682-775-02

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SMPLY™ sanitizer



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An Epic Essentials™ Brand
Manufactured by: Froggy's Fog
1536 N. Main St.
Mt. Pleasant, TN 38474
615.469.4906 • NDC: 75682-775-16



WWW.SMPLYBRANDS.COM

16 FL OZ (473 ml)

We clean up well
together.

473 mL NDC: 75682-775-16

Our Simple Story

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SMPLY™ sanitizer



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

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An Epic Essentials™ Brand
Manufactured by: Froggy's Fog
1536 N. Main St.
Mt. Pleasant, TN 38474
615.469.4906 • NDC: 75682-775-01



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1 US Gallon (3785 mL)

We clean up well
together.

3785 mL NDC: 75682-775-01

SMPLY ALOE HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC: 75682-775
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)				
ALOE (UNII: V5VD430YW9)				
GLYCERIN (UNII: PDC6A3C0OX)		1.45 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)		0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75682-775-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75682-775-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75682-775-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75682-775-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75682-775-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75682-775-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75682-775-64	1893 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
8	NDC:75682-775-55	208198 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
9	NDC:75682-775-25	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(75682-775)

