# SMPLY RENEW 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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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 RENEW Hand Sanitizer**

SMPLY.	Drug Facts ACTIVE INGREDIENTS PURPOSE Ethyl Alcohol 70% Antisepti
	USES Hand annihizer to belp reduce bacteris that potentially can cause disease. For use when soup and water are not available.
ENEW	WARNINGS For external uses only. Flammable. Keep away from heat or flame.
	DO NOT USE • on children legs than 2 months of age • on open stim wounds
pired by:	When tuing this product keep out of eyes, earn, and mouth. In case of contact with eyes, risue eyes thoroughly with water
GLEAF	Stop use and ask doctor if irritation or rash occurs. These may be signs of a serious condition.
NDALWOOD	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
SE PETAL	<ul> <li>on children less than 2 months of age</li> <li>on open skin wounds</li> <li>When using this product keep out of eyes, earn, and mouth. In case of contact with eyes, risec eyes thoroughly with water.</li> <li>Stop use and ask doctor if irritation or reach occurs. These may be signs of a sections condition.</li> <li>Keep out of reach of children. If swallowed, get medical help or contact a Physica Control Center right away.</li> <li>DIRECTIONS</li> <li>Place cnough product on hands to cover all surfaces. Run hands to get recire and direction in 5-300 (39-367).</li> <li>Stop reaction 15-300 (39-367).</li> <li>Stop reaction 15-300 (39-367).</li> <li>Stop relations.</li> <li>INACTIVE INGREDIENTS</li> </ul>
emium hand sanitizer spray th natural moisturizers and	OTHER INFORMATION • Store between 15-30G (59-86F). • Supervise children under 6 years of age when using this product to avoid swallowing.
egant fragrance. For use ien soap and water are t available.	INACTIVE INGREDIENTS fragrance, glycerin, hydrogen peroxide, purified water USP
	Manufactured by: Froggy's Fog 302 Rutherford Ln. Columbia, TN 38401 615.469.4906 • NDC: 75682-886-08
FL OZ (236 mL) 0% Alcohol Antiseptic	
opical Solution - Non-Sterile Solution	8 40472 11887 8

236mL NDC: 75682-886-08

# SMPLY.

# RENEW

Inspired by:

FIG LEAF

#### SANDALWOOD

#### ROSE PETAL

Premium hand sanitizer spray with natural moisturizers and elegant fragrance. For use when soap and water are not available.

4 FL OZ (118 mL) 70% Alcohol Antiseptic Topical Solution - Non-Sterile Solution

#### 118mL NDC: 75682-886-04

# SMPLY.

# RENEW

Inspired by:

FIG LEAF

SANDALWOOD

#### ROSE PETAL

Premium hand sanitizer spray with natural moisturizers and elegant fragrance. For use when soap and water are not available.

2 FL OZ (49 mL) 70% Alcohol Antiseptic Topical Solution - Non-Sterile Solution www.smplybrands.com

## Drug Facts

ACTIVE INGREDIENTS Ethyl Alcohol 70%	PURPOSE Antiseptic
USES Hand sanitizer to help reduce bacteria that po disease. For use when soap and water are not a	
WARNINGS For external uses only. Flammable. Keep away f	rom 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, cars, an contact with eyes, risec eyes thoroughly with water	
Stop use and ask doctor if irritation or rash signs of a scrious condition.	occurs. These may be
Keep out of reach of children, If awallowed, contact a Poison Control Center right away.	get medical help or
DIRECTIONS • Place enough product on hands to cover al together until dry. • Avoid freezing and excessive heat abov 40	
OTHER INFORMATION   Stort between 15-30G (59-86F).  Supervise children under 6 years of agt witte avoid swallowing.	icn using this product
INACTIVE INGREDIENTS fragrance, glycerin, hydrogen peroxide, pari	fied water USP

Manufactured by: Froggy's Fog 302 Rutherford Ln. Columbia, TN 38401 615.469.4906 · NDC: 75682-886-04



### Drug Facts

# ACTIVE INGREDIENTS Ethyl Alcohol 70%

USES Hand sanitizer to help reduce bacteris that potential disease. For use when soap and water are not availabl

PURPOSE Antiseptic

WARNINGS For external uses only. Flam mable. Keep away from heat or flam

DO NOT USE • on children less than 2 months of age • on open skin wounds

When using this product keep out of eyes, ears, contact with eyes, risse eyes thoroughly with wa

use and ask doctor if irritation or rash occurs. These may be of a serious condition.

out of reach of children. If awallowe et a Poison Control Center right away

DIRECTIONS

www.smplybrands.com

ace enough product on handa to cover all surface ther until dry. oid freezing and excessive heat abov 40C (104F) Ave

OTHER INFORMATION • Store between 15-30G (59-86F) • Supervise children under 6 year to avoid swallowing.

INACTIVE INGREDIENTS , glycerin, hydrogen peroxide, parified water USP

Manufactured by: Froggy's Fog 302 Rutherford Ln. Columbia, TN 38401 615.469.4906 · NDC: 75682-886-02



### 49 mL NDC: 75682-886-02

# SMPLY RENEW HAND SANITIZER

P	roduct Informa	ation									
P	roduct T ype		1	HUMAN OTC DRUG	Ite	m Code	(Source	)	NDC	NDC:75682-886	
R	oute of Administr	ation	-	ΓΟΡΙCAL							
Δ	ativo Ingradio	at/A ativ	o Moio								
A	ctive Ingredie			ent Name			Pacie	of Strongth		Strongth	
лт			•	HOL - UNII:3K9958V	0.00		ALCOHO	of Strength		Strength 70 mL in 100 mL	
In	active Ingredi	ents									
			Ing	redient Name					Str	Strength	
FI	<b>G</b> (UNII: TGD87RII2	U)									
GLYCERIN (UNII: PDC6A3C0OX) 1.45 mL in 10							0 mI	0 mL			
	HYDROGEN PERO XIDE (UNII: BBX060AN9V)0.125 mL in 100 mL										
	Y <b>DROGEN PEROX</b> ATER (UNII: 059QI		: BBX060	AN9V)				0.125 mL in 1	100 n	nL	
W	ATER (UNII: 059QI		: BBX060	AN9V)				0.125 mL in 1	100 n	nL	
W P				AN9V) Package Descripti	on		Marl	0.125 mL in 1 keting Start Date			
W. P. #	ATER (UNII: 059QI ackaging	F0KO0R)				ion	<b>Marl</b> 03/30/2	keting Start Date		Marketing End	
W P # 1	ATER (UNII: 059QI Ackaging Item Code NDC:75682-886-	F0KO0R) 49 mL ir Product	1 BOTTL	Package Descripti	t a Combina			<b>keting Start</b> Date 020		Marketing End	
W P 4 1 2 3	ATER (UNII: 059QI ackaging Item Code NDC:75682-886- 02 NDC:75682-886-	49 mL ir Product 118 mL i Product	1 BOTTL n 1 BOTTI	<b>Package Descripti</b> E, SPRAY; Type 0: Not	t a Combina ot a Combina	tio n	03/30/2	<b>Keting Start</b> <b>Date</b> 020 020		Marketing End	
W # 1 3	ATER (UNII: 059QI ackaging Item Code NDC:75682-886- 02 NDC:75682-886- 04 NDC:75682-886- 04	49 mL ir Product 118 mL i Product 236 mL Product	1 BOTTL n 1 BOTT in 1 BOTT	<b>Package Descripti</b> E, SPRAY; Type 0: Not LE, SPRAY; Type 0: No	t a Combina ot a Combina	tio n	03/30/2	<b>Keting Start</b> <b>Date</b> 020 020		Marketing End	
W P 1 2 3 N	ATER (UNII: 059QI ackaging Item Code NDC:75682-886- 02 NDC:75682-886- 04 NDC:75682-886- 08	49 mL ir Product 118 mL i Product 236 mL Product	1 BOTTL n 1 BOTT in 1 BOTT <b>tio n</b>	<b>Package Descripti</b> E, SPRAY; Type 0: Not LE, SPRAY; Type 0: No LE, SPRAY; Type 0: No	t a Combinat ot a Combina ot a Combina	atio n	03/30/24 03/30/24 03/30/24	<b>xeting Start</b> <b>Date</b> 020 020 020		Marketing End Date	
<ul> <li>W.</li> <li>P.</li> <li>#</li> <li>1</li> <li>2</li> <li>3</li> <li>M.</li> </ul>	ATER (UNII: 059QI ackaging Item Code NDC:75682-886- 02 NDC:75682-886- 04 NDC:75682-886- 04	49 mL ir Product 118 mL i Product 236 mL Product <b>forma</b>	1 BOTTL n 1 BOTT in 1 BOTT <b>tio n</b>	<b>Package Descripti</b> E, SPRAY; Type 0: Not LE, SPRAY; Type 0: No	t a Combinat ot a Combina ot a Combina	tion tion	03/30/24 03/30/24 03/30/24	keting Start Date 020 020 020		Marketing End	

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(75682-886)					