

## **SMPLY SANITIZER PEPPERMINT- 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.*

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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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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 Peppermint

**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

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

**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.

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

**DO NOT USE**  
• on children less than 2 months of age  
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When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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**DIRECTIONS**  
• Place enough product on hands to cover all surfaces. Rub hands together until dry.  
• Avoid freezing 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 copolymer, aminomethyl propanol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP

An Epic Essentials™ Brand  
302 Rutherford Ln, Columbia, TN 38401  
675.469.4906  
NDC: 75682-668-01

8 40472 11841 0

1 US Gallon (3785 mL) We clean up well together.

3785 mL NDC: 75682-668-01



### 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



**Peppermint 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
<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>DON'T USE</b> - 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.	
<b>DIRECTIONS</b> - Place enough product on hands to cover all surfaces. Rub hands together until dry. - Avoid breathing 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 polymers, amibuthylpropionol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

An Epic Essentials™ Brand  
302 Rutherford Ln, Columbia, TN 38401  
615.469.4906  
NDC: 75682-668-64



1893 mL NDC: 75682-668-64



### 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



**Peppermint 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
<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>DON'T USE</b> - 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.	
<b>DIRECTIONS</b> - Place enough product on hands to cover all surfaces. Rub hands together until dry. - Avoid breathing 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 polymers, amibuthylpropionol, fragrance, glycerin, hydrogen peroxide, polyethylene glycol, purified water USP	

An Epic Essentials™ Brand  
302 Rutherford Ln, Columbia, TN 38401  
615.469.4906  
NDC: 75682-668-32



946 mL NDC: 75682-668-32

## 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



**Peppermint 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
<b>INDICATIONS</b> Hand sanitizer to help reduce bacterial pathogens on casual surfaces. For use when soap and water are not available.	
<b>WARNINGS</b> For external use only. Flammable. Keep away from heat or flame.	
<b>PRECAUTIONS</b> - Use children less than 2 months of age - Use open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<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 breathing and excessive heat above 40°C (104°F)	
<b>OTHER INFORMATION</b> - Store between 15-30°C (59-86°F). - Supervise children under 6 years of age when using this product to avoid swallowing.	
<b>ACTIVE INGREDIENTS</b> acrylate polymers, antimicrobial preservatives, fragrance, glycerin, hydroxyacetone, polyethylene glycol, purified water USP	

An Epic Essentials® Brand  
300 Rutherford Ln, Columbia, TN 38401  
615.659.4906  
NDC 75682-668-16



473 mL NDC: 75682-668-16

## 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



**Peppermint 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
<b>INDICATIONS</b> Hand sanitizer to help reduce bacterial pathogens on casual surfaces. For use when soap and water are not available.	
<b>WARNINGS</b> For external use only. Flammable. Keep away from heat or flame.	
<b>PRECAUTIONS</b> - Use children less than 2 months of age - Use open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<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 breathing and excessive heat above 40°C (104°F)	
<b>OTHER INFORMATION</b> - Store between 15-30°C (59-86°F). - Supervise children under 6 years of age when using this product to avoid swallowing.	
<b>ACTIVE INGREDIENTS</b> acrylate polymers, antimicrobial preservatives, fragrance, glycerin, hydroxyacetone, polyethylene glycol, purified water USP	

An Epic Essentials® Brand  
300 Rutherford Ln, Columbia, TN 38401  
615.659.4906 | NDC 75682-668-08



236 mL NDC: 75682-668-08



**Our Simple Story**

SPLY 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.

**SPLY**

**SPLY™**

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 illness. For use when soap and water are not available.

**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 use on open skin wounds

**When using flammable liquid, out of eyes, ears, and mouth, in case of contact with eyes, close 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.**

**CONTENTS**  
- 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).  
- Supersaturate children under 6 years of age when using this product to avoid swallowing.

**ACTIVE INGREDIENTS**  
ethylene glycol, water, methyl paraben, fragrance, glycerin, hydroxy paraben, polyethylene glycol, purified water, etc.

An Epic Essentials™ Brand  
302 Rutherford Ln., Columbia, TN 38401  
615.469.4906  
NDC: 75682-668-04

118 mL NDC: 75682-668-04

**Our Simple Story**

SPLY 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.

**SPLY**

**SPLY™**

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 illness. For use when soap and water are not available.

**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 use on open skin wounds

**When using the product, keep out of eyes, ears, and mouth, in case of contact with eyes, close 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.**

**CONTENTS**  
- 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).  
- Supersaturate children under 6 years of age when using this product to avoid swallowing.

**ACTIVE INGREDIENTS**  
ethylene glycol, water, methyl paraben, fragrance, glycerin, hydroxy paraben, polyethylene glycol, purified water, etc.

An Epic Essentials™ Brand  
302 Rutherford Ln., Columbia, TN 38401  
615.469.4906  
NDC: 75682-668-02

59 mL NDC: 75682-668.02

## SPLY SANITIZER PEPPERMINT

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75682-668
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	
PEPPERMINT (UNII: V95R5KMY2B)	
RAPIDGEL EZ1 (UNII: 33JH4A7R2K)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75682-668-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75682-668-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75682-668-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75682-668-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75682-668-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75682-668-64	1893 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75682-668-01	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(75682-668)