

SMPLY BLACK VELVET 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 Black Velvet Hand Sanitizer

Our Simple Story

SMPLY Sanitizer was created so you can live freely and live fully. From 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

Black Velvet
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
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DIRECTIONS
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- 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 polymer, aminoethyl propanol, fragrance, glycerin, polyethylene glycol, purified water USP

An Epic Essentials™ Brand
Distributed by: SPLY.
1536 N. Main St.
Mt. Pleasant, TN 38474
615.393.6700 • NDC: 75682-603-02

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

8 40472 12602 6

59mL NDC: 75682-603-02



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.

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



SMPLY™

sanitizer

Black Velvet 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 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	
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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 (50-86F). - Supervise children under 6 years of age when using this product to avoid swallowing.	
INACTIVE INGREDIENTS acrylate polymer, aminoethyl propanol, fragrance, glycerin, polyethylene glycol, purified water USP	

An Epic Essentials™ Brand
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1536 N. Main St.,
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8 40472 12603 3

118mL NDC: 75682-603-04



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.

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SMPLY™

sanitizer

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

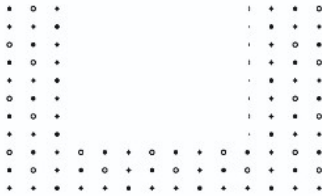
8 FL. OZ (236 ml)

We clean up well together.

Drug Facts	
ACTIVE INGREDIENTS Ethyl Alcohol 70% v/v	PURPOSE Antiseptic
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8 40472 12604 0

236mL NDC: 75682-603-08



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 SPLY.



SMPLY™

sanitizer



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

Drug Facts

ACTIVE INGREDIENTS	PURPOSE
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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 polymer, ammoniethyl propanol, fragrances, glycerin, polyethylene glycol, purified water USP	

An Epic Essentials™ Brand
Distributed by: SPLY.
1536 N. Main St.
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615.393.6700 • NDC: 75682-603-16

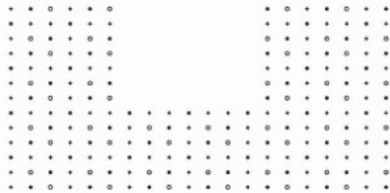


WWW.SMPYBRANDS.COM

16 FL OZ (473 ml)

We clean up well together.

473mL NDC: 75682-603-16



Our Simple Story

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SMPLY™

sanitizer



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

Drug Facts

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An Epic Essentials™ Brand
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1536 N. Main St.
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615.393.6700 • NDC: 75682-603-32

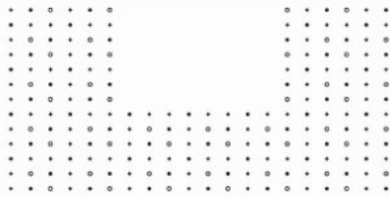


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32 FL OZ (946 mL)

We clean up well together.

946mL NDC: 75682-603-32



Our Simple Story

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SMPLY™

sanitizer



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

WWW.SMPLYBRANDS.COM

1 US Gallon (3785 mL)

We clean up well
together.

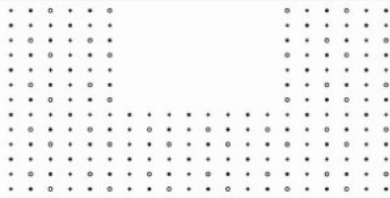
Drug Facts

ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 70% v/v	Antiseptic
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INACTIVE INGREDIENTS acrylate polymers, aminoethyl propanol, fragrance, glycerin, polyethylene glycol, purified water USP	

An Epic Essentials™ Brand
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1536 N. Main St.,
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615.393.6700 • NDC: 75682-603-01



3785mL NDC: 75682-603-01



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



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

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50 Gallons (189271 mL)

We clean up well
together.

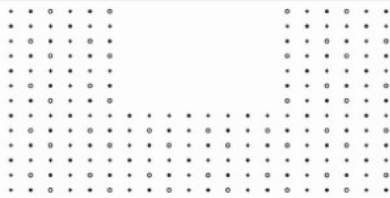
Drug Facts

ACTIVE INGREDIENTS	PURPOSE
Ethyl Alcohol 70% v/v	Antiseptic
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An Epic Essentials™ Brand
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615.393.6700 • NDC: 75682-603-50



189271mL NDC: 75682-603-50



Our Simple Story

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SMPLY™

sanitizer



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

Drug Facts

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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, ammonium propanol, fragrance, glycerin, polyethylene glycol, purified water USP	

An Epic Essentials™ Brand
 Distributed by: SMPLY,
 1536 N. Main St.,
 Mt. Pleasant, TN 38474
 615.393.6700 • NDC: 75682-603-25



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250 Gallons (946353 mL)

We clean up well together.

946353 mL NDC: 75682-603-25

SMPLY BLACK VELVET HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75682-603
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)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
DIHYDROMYRCENOL (UNII: 46L1B02ND9)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
METHYL DIHYDROJASMONATE (SYNTHETIC) (UNII: 3GW44CIE3Y)	
JUNIPERUS DEPPEANA WOOD OIL (UNII: 4739QA5686)	
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:75682-603-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75682-603-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75682-603-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75682-603-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75682-603-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75682-603-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75682-603-50	189271 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
8	NDC:75682-603-25	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(75682-603)

Revised: 3/2021

Froggy's Fog LLC