

**HAND SANITIZER- alcohol liquid**  
**SATELLITE SPIRITS INC.**

*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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**Hand Sanitizer**

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)**

Denatured Ethyl Alcohol 80% v/v. Purpose: Antimicrobial

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

To help reduce bacteria on the skin.

**Warnings**

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

**Do not use**

- In or near the eyes. If contact occurs, rinse thoroughly with water.

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.

Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

## Directions

- Apply to hands, rub together until dry.

## Other information


- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

3.79L NDC: 77443-001-06



**SOUTH FORK**<sup>TM</sup>

**HAND SANITIZER**  
NON-STERILE SOLUTION

ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION  
1 GAL (3.79 L)

473 ml NDC: 77443-001-03

## Drug Facts

**Active ingredients:**  
Denatured Ethyl Alcohol

**Uses**  
To help reduce bacteria

**Warnings**  
Flammable, keep away  
For external use only.  
Do not use in or near the  
with water.

Stop use and ask a doctor  
Irritation or rash develop  
Keep out of reach of children  
If swallowed, get medical  
Center right away.

**Directions:** Apply to  
**Other information:** Av  
40C (104F). Store betwe  
**Inactive ingredient**  
Glycerin, Hydrogen perc

30% of all sanitizers  
responders

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Produced in accordance with  
and Centers for Disease C



**DO NOT DRINK**

Batch #

MFG 05/03/2020-0

Distributed by Satellite

(916) 770 - 6955

www.



**SOUTH FORK™**  
**HAND SANITIZER**  
 NON-STERILE SOLUTION

ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION  
 16 FL oz (473 mL)

**Drug Facts**

**Active ingredients**  
 Denatured Ethyl Alcohol 80% w/v.....

**Uses**  
 To help reduce bacteria on the skin.

**Warnings**  
 Flammable, keep away from flame.  
 For external use only.  
 Do not use in or near the eyes. If contact with water.  
 Stop use and ask a doctor if Irritation or rash develops and lasts

**Directions:** Apply to hands, rub together

**Other information:** Avoid freezing and 40C (104F). Store between 15-30C (59-86F)

**Inactive ingredients**  
 Glycerin, Hydrogen peroxide, Water

Produced in accordance with World Health Organization Guidelines for Hand Sanitizers  
 Centers for Disease Control and Prevention (CDC)

**DO NOT DRINK  
 NOT FOR CONSUMPTION**

16 FL OZ (473 mL)  
 Batch # 1 33

MFG 05/03/2020-05/10/2020  
 Distributed by Satellite Spirits Inc. Gr  
 (916) 770 - 6959 • info@satell  
 www.southforkvodka

375 ml NDC: 77443-001-02



**SOUTH FORK™**  
**HAND SANITIZER**  
 NON-STERILE SOLUTION

ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION  
 12.7 FL oz (375 mL)

**Drug Facts**

**Active ingredients**  
 Denatured Ethyl Alcohol 80% w/v.....

**Uses**  
 To help reduce bacteria on the skin.

**Warnings**  
 Flammable, keep away from flame.  
 For external use only.  
 Do not use in or near the eyes. If contact with water.  
 Stop use and ask a doctor if Irritation or rash develops and lasts

**Directions:** Apply to hands, rub together

**Other information:** Avoid freezing and 40C (104F). Store between 15-30C (59-86F)

**Inactive ingredients**  
 Glycerin, Hydrogen peroxide, Water

Produced in accordance with World Health Organization Guidelines for Hand Sanitizers  
 Centers for Disease Control and Prevention (CDC)

**DO NOT DRINK  
 NOT FOR CONSUMPTION**

12.7 FL OZ (375 mL)  
 Batch # 1 33

MFG 05/03/2020-05/10/2020  
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 www.southforkvodka

236 ml NDC: 77443-001-01



**Drug Facts**

**Active ingredients**  
Denatured Ethyl Alcohol 80% w/v.....

**Uses**  
To help reduce bacteria on the skin.

**Warnings**  
Flammable, keep away from flame.  
For external use only.  
Do not use in or near the eyes. If contact with water.  
Stop use and ask a doctor if Irritation or rash develops and lasts

Keep out of reach of children  
If swallowed, get medical help or contact Center right away.

**Directions:** Apply to hands, rub together

**Other information:** Avoid freezing and 40C (104F). Store between 15-30C (59-86F).

**Inactive ingredients**  
Glycerin, Hydrogen peroxide, Water

Produced in accordance with World Health Organization Guidelines for Hand Sanitizers  
Centers for Disease Control and Prevention (CDC)

**DO NOT DRINK  
NOT FOR CONSUMPTION**  
8 FL OZ (236 mL)

Batch # 1 33

MFG 05/03/2020-05/10/2020  
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www.southforkvodka

750 ml NDC: 77443-001-04



**Drug Facts**

**Active ingredients**  
Denatured Ethyl Alcohol 80% w/v.....

**Uses**  
To help reduce bacteria on the skin.

**Warnings**  
Flammable, keep away from flame.  
For external use only.  
Do not use in or near the eyes. If contact with water.  
Stop use and ask a doctor if Irritation or rash develops and lasts

Keep out of reach of children  
If swallowed, get medical help or contact Center right away.

**Directions:** Apply to hands, rub together

**Other information:** Avoid freezing and 40C (104F). Store between 15-30C (59-86F).

**Inactive ingredients**  
Glycerin, Hydrogen peroxide, Water

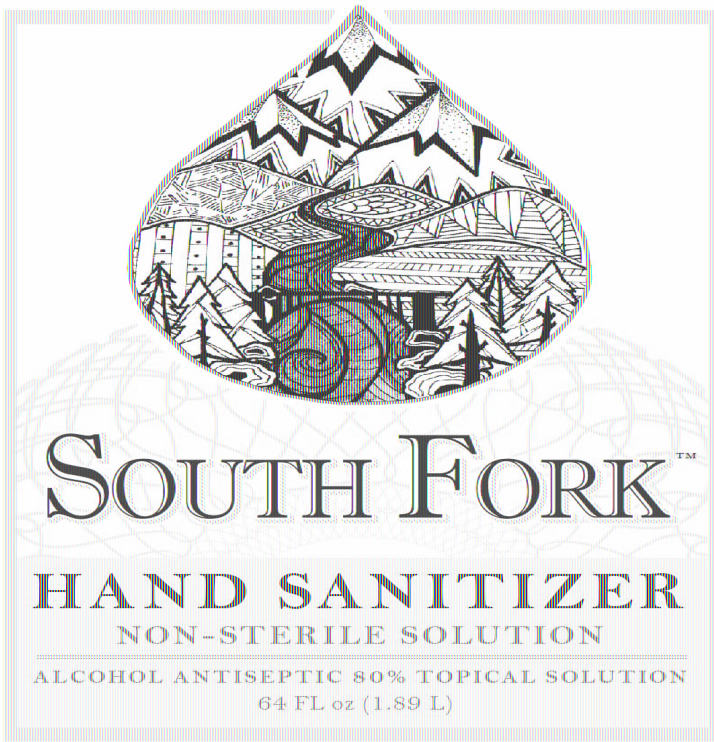
Produced in accordance with World Health Organization Guidelines for Hand Sanitizers  
Centers for Disease Control and Prevention (CDC)

**DO NOT DRINK  
NOT FOR CONSUMPTION**  
25 FL OZ (750 mL)

Batch # 1 33

MFG 05/03/2020-05/10/2020  
Distributed by Satellite Spirits Inc. Gr  
(916) 770 - 6959 • info@satell  
www.southforkvodka

1.89 L NDC: 77443-001-05



30% of all sanitizer produced is donated to first responders and medical facilities. WE'RE IN THIS TOGETHER! - The South Fork Team

<b>Drug Facts</b>
<b>Active ingredient</b> Denatured Ethanol
<b>Uses</b> To help reduce germs on your hands
<b>Warnings</b> Flammable, Irritant For external use only Do not use in children's hands with water. Stop use and throw away if you experience Irritation or rash
<b>Directions</b> Other information 40C (104F), 50C (122F) <b>Inactive ingredients</b> Glycerin, Hydroxyethyl Cellulose
Produced in accordance with the standards of the Centers for Disease Control and Prevention
<b>DO NOT DRINK</b> <b>NOT FOR CONSUMPTION</b> 64 FL OZ (1.89 L) Batch # MFG 05/0 Distributed by (916)

## HAND SANITIZER

alcohol liquid

Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77443-001
<b>Route of Administration</b>	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 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: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77443-001-01	236 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	04/22/2020	
2	NDC:77443-001-02	375 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	04/22/2020	
	NDC:77443-001-03	473 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		

3	NDC:77443-001-03	473 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/22/2020	
4	NDC:77443-001-04	750 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	04/22/2020	
5	NDC:77443-001-05	1890 mL in 1 JUG; Type 0: Not a Combination Product	04/22/2020	
6	NDC:77443-001-06	3790 mL in 1 JUG; Type 0: Not a Combination Product	04/22/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/22/2020	

**Labeler** - SATELLITE SPIRITS INC. (087678606)

## Establishment

Name	Address	ID/FEI	Business Operations
SATELLITE SPIRITS INC.		087678606	manufacture(77443-001)

Revised: 5/2020

SATELLITE SPIRITS INC.