FRESH HAND SANITIZER- alcohol solution Speakeasy Spirits, 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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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right

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)

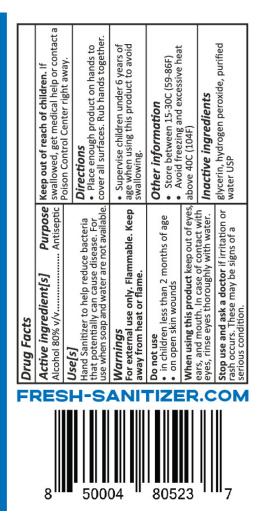
Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

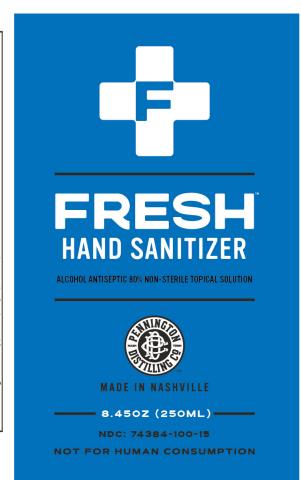
100 mL NDC: 74384-100-15

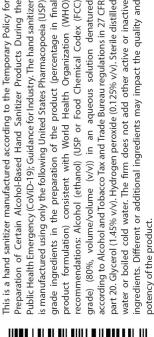
This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Gattain Activation and the Public Health Emergency (CoVID-19); Guidance Products During the Public Health Emergency (CoVID-19); Guidance Products Order an antiactured using only the following United States Pharmacopeal (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization WHO) recommendations. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (180%, volume/volume (viv.)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20. Glycerol (145% viv.). Hydrogen peroxide (0.125% viv.). 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.

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not available When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with **keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center Supervise children under 6 years of age when using this product to avoid swallowing or rash occurs. These may be signs of a serious Place enough product on hands to cover all surfaces. Rub hands together until dry. Hand Sanitizer to help reduce bacteria that potentially can cause disease. For *Inactive ingredients* glycerin, hydrogen peroxide, purified water USP Flammable. Keep away from heat or flam Avoid freezing and excessive heat above 40C (104F) in children less than 2 months of Store between 15-30C (59-86F) use and ask a doctor Active ingredient[s] Alcohol 80% v/v..... Other information external use only.





FRESH-SANITIZER.COM

100 mL NDC: 74384-100-14



Drug Facts

Active ingredient[s]

Alcohol 80% v/v..... Antiseptic

use when soap and water are not available

Warnings

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

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

Purpose

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For

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.

Keep out of reach of children. If swallowed, get medical help or contact a

Poison Control Center right away. Place enough product on hands to cover all surfaces. Rub hands together.

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

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(0.125% v/v). 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]

Purpose

Use[s]

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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Do not use

- · in children less than 2 months of age
- · on open skin wounds

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Directions

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Other information

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Manufacturing Date:

Batch Number:

118 mL NDC: 74384-100-12



Active ingredient[s]

Purpose

Use[s]

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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Do not use

- · in children less than 2 months of age
- · on open skin wounds

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Directions

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Other information

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

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Manufacturing Date:

Batch Number:

4 mL NDC: 74384-100-11



NOT FOR HUMAN CONSUMPTION

Active ingredient[s]

Purpose

Use[s]

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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Do not use

- · in children less than 2 months of age
- · on open skin wounds

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Other information

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

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Manufacturing Date: Batch Number:



ALCOHOL ANTISEPTIC 80% | NON-STERILE TOPICAL SOLUTION

____ 750 ML ____

NDC: 74384-100-10

MADE IN NASHVILLE



VODKA

UNLIKE OUR SPIRITS, THIS PRODUCT IS NOT FOR HUMAN CONSUMPTION

Active ingredient[s]

Purpose

Use[s]

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.

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Directions

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- · 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

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Manufacturing Date: Batch Number:



3.785 L NDC: 74384-100-08

Active ingredient[s]

Purpose

Use[s]

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.

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Directions

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- · 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

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: 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. Glycerol (1.45% v/v). Hydrogen peroxide (0.125% v/v). 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.

Manufacturing Date: Batch Number:

3.785 L NDC: 74384-100-08



ALCOHOL ANTISEPTIC 80% | NON-STERILE TOPICAL SOLUTION

- 1 GALLON (3.785 L) -

NDC: 74384-100-08

MADE IN NASHVILLE



UNLIKE OUR SPIRITS, THIS PRODUCT IS NOT FOR HUMAN CONSUMPTION

18.93 L NDC: 74384-100-07

Active ingredient[s]

Purpose

Use[s]

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.

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

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: 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. Glycerol (1.45% v/v). Hydrogen peroxide (0.125% v/v). 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.

Manufacturing Date: Batch Number:

18.93 L NDC: 74384-100-07



ALCOHOL ANTISEPTIC 80% | NON-STERILE TOPICAL SOLUTION

5 GALLONS (18.93L)

NDC: 74384-100-07

MADE IN NASHVILLE



UNLIKE OUR SPIRITS, THIS PRODUCT IS
NOT FOR HUMAN CONSUMPTION

Active ingredient[s]

Purpose

Use[s]

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.

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

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Manufacturing Date:

Batch Number:

50 mL NDC: 74384-100-06





ALCOHOL ANTISEPTIC 80%

NDC: 74384-100-06

NON-STERILE TOPICAL SOLUTION MADE IN NASHVILLE, TENN

UNLIKE OUR SPIRITS, THIS PRODUCT IS NOT FOR HUMAN CONSUMPTION

Active ingredient[s]

Purpose

Use[s]

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.

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

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Manufacturing Date: Batch Number:



ALCOHOL ANTISEPTIC 80% | NON-STERILE TOPICAL SOLUTION



MADE IN NASHVILLE

- 750 ML -

NDC: 74384-100-05

NOT FOR HUMAN CONSUMPTION

Active ingredient[s]

Purpose

Use[s]

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.

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

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Manufacturing Date: Batch Number:



ALCOHOL ANTISEPTIC 80% | NON-STERILE TOPICAL SOLUTION



MADE IN NASHVILLE

- 1 LITER ---

NDC: 74384-100-04

NOT FOR HUMAN CONSUMPTION

3.785 L NDC: 74384-100-03

Active ingredient[s]

Purpose

Use[s]

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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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.

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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

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Manufacturing Date: Batch Number:

3.875 L NDC: 74384-100-03



ALCOHOL ANTISEPTIC 80% | NON-STERILE TOPICAL SOLUTION



MADE IN NASHVILLE

- 1 GALLON (3.785 L) ----

NDC: 74384-100-03

NOT FOR HUMAN CONSUMPTION

18.93 L NDC: 74384-100-02

Active ingredient[s]

Purpose

Use[s]

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.

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

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Manufacturing Date: Batch Number:

18.93 L NDC:74384-100-02



ALCOHOL ANTISEPTIC 80% | NON-STERILE TOPICAL SOLUTION



MADE IN NASHVILLE

5 GALLONS (18.93L)

NDC: 74384-100-02

NOT FOR HUMAN CONSUMPTION

Active ingredient[s]

Purpose

Use[s]

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
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Manufacturing Date: Batch Number:



ALCOHOL ANTISEPTIC 80% | NON-STERILE TOPICAL SOLUTION



MADE IN NASHVILLE

- 264.2 GAL (1000 L) ---

NDC: 74384-100-01

NOT FOR HUMAN CONSUMPTION

FRESH HAND SANITIZER

alcohol solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74384-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
ALCOHOL (UN	II: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL	
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL	
WATER (UNII: 059QF0KO0R)		

Product Characteristics		
Color	Score	
Shape	Size	
Flavor	Imprint Code	
Contains		

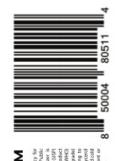
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Packaging					
# Item Code		Package Description	Marketing Start Date	Marketing End Date	
1	NDC:74384-100- 01	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020		
2	NDC:74384-100- 02	18927 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020		
3	NDC:74384-100- 03	3785 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020		
4	NDC:74384-100- 04	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
5	NDC:74384-100- 05	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
6	NDC:74384-100- 06	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
7	NDC:74384-100- 07	18927 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020		
8	NDC:74384-100- 08	3785 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020		
9	NDC:74384-100- 09	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
10	NDC:74384-100- 10	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
11	NDC:74384-100- 11	4 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020		
12	NDC:74384-100- 12	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
12	NDC:74384-100-	118 mL in 1 ROTTLE: Type 0: Not a Combination Product	Λ <i>λ</i> /10/20 20		

13	13	110 IIIL III 1 DO I I LE, 19PE O. MOCA COMOMARION FIORUCC	U4/13/2U2U	
14	NDC:74384-100- 15	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2020	
1.5	NDC:74384-100- 16	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/02/2020	

Active ingredient(s) Purpose Active ingredient(s) Purpose Active ingredient in the potentially can cause disease. For use when soap and water are not available. Warnings
See[5] Varnings Varnings
Varnings
For external use only. Hammable, Keep away from heat or flame
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.
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 peraxide, purified water USP
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Marketing Information

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

Labeler - Speakeasy Spirits, LLC (036373552)

Establishment				
Name	Address	ID/FEI	Business Operations	
Speakeasy Spirits, LLC		036373552	manufacture(74384-100)	

Revised: 7/2020 Speakeasy Spirits, LLC