

HAND SANITIZER- isopropyl alcohol liquid

Uncle Jumbo's Distillery, 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.

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.

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

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

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.

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. These may be signs of a serious condition.

Other information

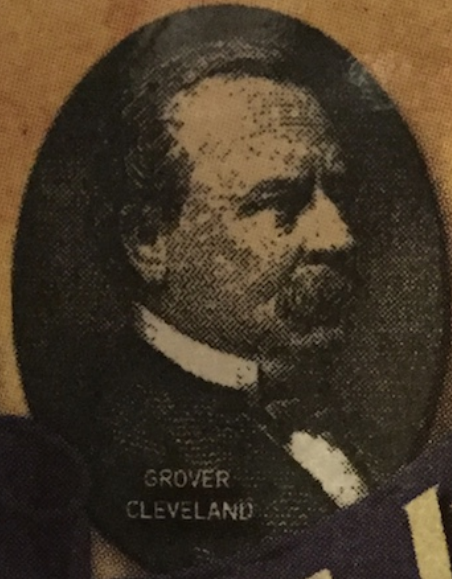
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

BOTTLING OUR
COUNTRY'S SPIRIT!



GROVER
CLEVELAND

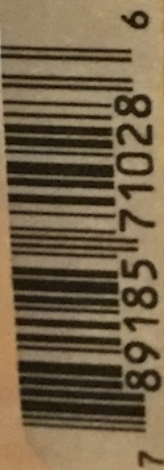
UNCLE JUMBO'S



American Vodka
HAND SANITIZER

250mL

Manufactured in accordance with WHO and FDA standards. Emergency Supply.
DISTILLED AND BOTTLED BY UNCLE JUMBO'S DISTILLERY, INC., CLARENCE CENTER, NY, USA



7 89185 71028 6

Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-sterile Solution 250ML

Drug Facts**Active Ingredient(s)**

Alcohol 80% v/v.....

Purpose

.....Antiseptic

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.

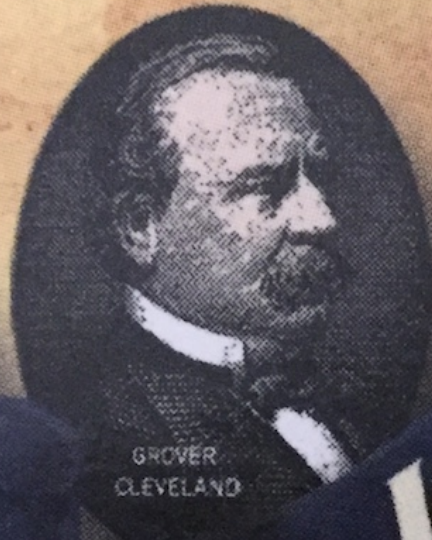
Other information

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

250 mL NDC: 75526-000-00

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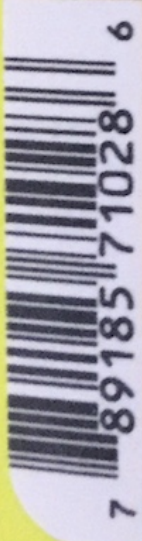
UNCLE JUMBO'S



American Vodka
HAND SANITIZER

12 oz (354mL)

Manufactured in accordance with WHO and FDA standards. Emergency Supply.
DISTILLED AND BOTTLED BY UNCLE JUMBO'S DISTILLERY, INC., CLARENCE CENTER, NY, USA



7 89185 71028 6

Alcohol Antiseptic 80%
Topical Solution
Hand Sanitizer
Non-sterile Solution
12 OZ (354mL)

Drug Facts

Active Ingredient[s]

Alcohol 80% v/v.....

Purpose

Antiseptic

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

Inactive Ingredients glycerin, hydrogen peroxide, purified water USP

Uncle Jumbo's Hand Sanitizer

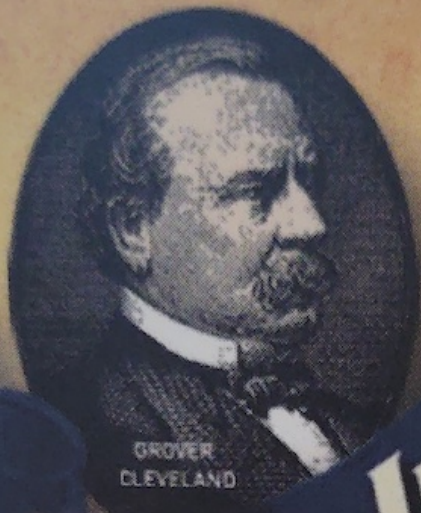
3890 ML

Drug Facts: Active Ingredient: Alcohol 80%...Sanitizer

Use(s)Hand Sanitizer to help reduce bacteria that potentially can cause disease. **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. They may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact poison control. **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 excessive heat above 40C (104F). **Inactive ingredients:** glycerin, hydrogen peroxide, purified water.

3890 ML 75526-000-01

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GROVER
CLEVELAND

UNCLE JUMBO'S



American Vodka
HAND SANITIZER

1.75 L (59.17 FL. OZ.)

DISTILLED AND BOTTLED BY UNCLE JUMBO'S DISTILLERY, INC., CLARENCE CENTER, NY, USA
Manufactured in accordance with WHO and FDA standards. Emergency Supply



Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-sterile Solution

1.75 L (59.17 FL. OZ.)

Drug Facts

Active Ingredient(s)

Alcohol 80% v/v

Purpose

Antiseptic

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

1750ml 1.75 L front & Back

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-sterile Solution

200 ml

Drug Facts

Active Ingredient(s)

Alcohol 80% v/v.....

Purpose

Antiseptic

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

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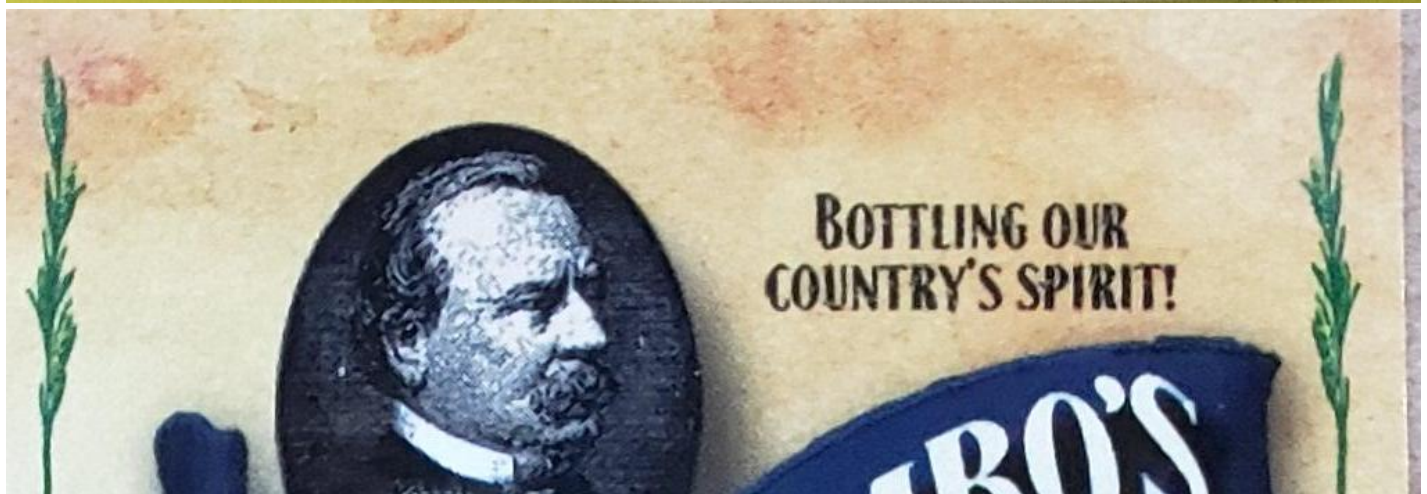
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Inactive Ingredients glycerin, hydrogen peroxide, purified water USP



GROVER
CLEVELAND

UNCLE JUMBO'S



American Vodka
HAND SANITIZER

200mL

**DISTILLED AND BOTTLED BY
UNCLE JUMBO'S DISTILLERY, INC.,
CLARENCE CENTER, NY, USA**



7 89185 71028 6

Manufactured in accordance
with WHO and FDA standards.
Emergency Supply

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COUNTRY'S SPIRIT!



UNCLE JUMBO'S



American Vodka
HAND SANITIZER



473 ml (16 fl oz)

DISTILLED AND BOTTLED BY UNCLE JUMBO'S DISTILLERY, INC., CLARENCE CENTER, NY, USA
Manufactured in accordance with WHO and FDA standards. Emergency Supply.

Alcohol Antiseptic 80%
Topical Solution
Hand Sanitizer
Non-sterile Solution
16 FL OZ (473mL)

Drug Facts

Active Ingredient(s)

Alcohol 80% v/v.....

Purpose

Antiseptic

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

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- on open skin wounds

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Other information

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

473 ml Front & Back

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-sterile Solution

946352 ml (250 Gal.)

Drug Facts

Active Ingredient(s)

Alcohol 80% v/v.....

Purpose

Antiseptic

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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Other information

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Inactive Ingredients glycerin, hydrogen peroxide, purified water USP



946352 ml front & back

HAND SANITIZER

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75526-000
Route of Administration	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: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75526-000-00	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75526-000-01	3890 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75526-000-02	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75526-000-03	200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75526-000-04	946352 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75526-000-05	473 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75526-000-06	1750 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; 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 - Uncle Jumbo's Distillery,Inc (090743531)

Establishment

Name	Address	ID/FEI	Business Operations
Uncle Jumbo's Distillery Inc		090743531	manufacture(75526-000)

Revised: 5/2020

Uncle Jumbo's Distillery,Inc