

**HAND SANITIZER- alcohol antiseptic 80% hand sanitizer liquid**  
**Caribbean Distillers 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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**Hand Sanitizer - WHO**

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

**55 gallon Drum Package Label - Principal Display Panel**

208.198 L NDC: 74092-280-04



**Alcohol Antiseptic 80%  
Topical Solution**

**Hand Sanitizer  
Non-sterile Solution  
#74092-280-04  
(55 Gallons)  
208,198 mL  
For Consumer Use**

Manufactured by  
Caribbean Distillers, LLC  
425 Recker Highway  
Auburndale, FL 33823

<b>Drug Facts</b>	
<b>Active ingredient(s)</b> Alcohol 80% v/v.....	<b>Purpose</b> .....Antiseptic
<b>Use(s)</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame</b> Do not use	
<ul style="list-style-type: none"> <li>• In children less than 2 months of age</li> <li>• On open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
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<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
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**265 gallon Tote**



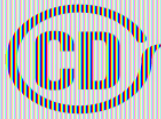
**Alcohol Antiseptic 80%  
Topical Solution**  
  
**Hand Sanitizer  
Non-sterile Solution  
#74092-280-05  
(265 Gallons)  
1,003,134.12276 mL  
For Consumer Use**

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 Caribbean Distillers, LLC  
 425 Recker Highway  
 Auburndale, FL 33823

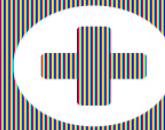
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1003.13 L NDC: 74092-280-05

1.5 ltr Plastic



CARIBBEAN  
DISTILLERS



# HAND SANITIZER

Alcohol Antiseptic

80%

Topical Solution

Non-sterile Solution

1.50L

WARNING: FLAMMABLE. Keep away from heat, spark, electrical fire or flame.



**HAND SANITIZER** Alcohol Antiseptic 80% • Topical Solution • Non-sterile

## Drug Facts

### Active ingredient[s]

Denatured Ethyl Alcohol 80% w/v.....Antiseptic (antimicrobial)

### Purpose

### Use[s]

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap

### Warnings

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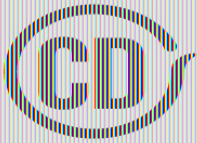
### Other information

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

**Inactive ingredients:** water, glycerin, hydrogen peroxide

Manufactured by: Caribbean Distillers, LLC. 425 Recker Hwy, Auburndale, FL 3

1.75L Plastic



CARIBBEAN  
DISTILLERS



# HAND SANITIZER

Alcohol Antiseptic

# 80%

Topical Solution

Non-sterile Solution

1.75L

WARNING  
FLAMMABLE Keep away from heat, spark,  
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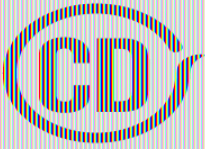
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Manufactured by: Caribbean Distillers, LLC. 425 Recker Hwy, Auburndale, FL 338

1L Plastic



CARIBBEAN  
DISTILLERS



# HAND SANITIZER

Alcohol Antiseptic

80%

Topical Solution

Non-sterile Solution

1.00L

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## HAND SANITIZER

alcohol antiseptic 80% hand sanitizer liquid



## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74092-280
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	8000 L in 10000 L

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	145 L in 10000 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	4.17 L in 10000 L
WATER (UNII: 059QF0K00R)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:74092-280-01	0.75 L in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	04/02/2020	
2	NDC:74092-280-02	1 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/02/2020	
3	NDC:74092-280-03	18.927 L in 1 PAIL; Type 0: Not a Combination Product	04/02/2020	
4	NDC:74092-280-04	208.198 L in 1 DRUM; Type 0: Not a Combination Product	04/02/2020	
5	NDC:74092-280-05	1003.13 L in 1 DRUM; Type 0: Not a Combination Product	04/02/2020	
6	NDC:74092-280-13	1 in 1 BOX	05/06/2020	
6	NDC:74092-280-06	3 L in 1 BAG; Type 0: Not a Combination Product		
7	NDC:74092-280-07	1.75 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/06/2020	
8	NDC:74092-280-09	1.5 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/06/2020	
9	NDC:74092-280-11	18.925 L in 1 BAG; Type 0: Not a Combination Product	04/15/2020	
10	NDC:74092-280-00	1 in 1 BOX	05/06/2020	
10	NDC:74092-280-12	3 L in 1 BAG; Type 1: Convenience Kit of Co-Package		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	04/02/2020	

**Labeler** - Caribbean Distillers LLC (968074257)

**Registrant** - Caribbean Distillers LLC (968074257)

**Establishment**

Name	Address	ID/FEI	Business Operations
Caribbean Distillers LLC		968074257	manufacture(74092-280)

Revised: 5/2020

Caribbean Distillers LLC