

**HAND SANITIZER- alcohol liquid**  
**Club Caribe 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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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

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

3000mL Family Pack NDC: 74336-180-05



<b>CD</b> <b>HAND SANITIZER</b> <b>Alcohol Antiseptic 80%</b> <b>Topical Solution</b> Non-sterile Solution 3000 ml. (3L.)	
<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Denatured Ethyl Alcohol 80% v/v.....	Antiseptic (antimicrobial)
<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>	
For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b>	
• in children less than 2 months of age • on open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children</b> . If swallowed, get medical help or contact a Poison Control Center right away 1 (800) 222-1222	
<b>Directions</b>	
• Place enough product on hands to cover all surfaces. • Rub hands together until dry. • Supervise children under 6 years of age when using to avoid swallowing. • Repeat as necessary.	
<b>Other information</b>	
• Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
<b>Inactive ingredients:</b> water, glycerin, hydrogen peroxide	
Manufactured by: Caribbean Distillers, LLC Carr. 172 Km 9.1 Cidra, P.R. 00739 Tel: 787-739-7100	

## Package Label - Principal Display Panel

250ML NDC: 74336-180-06

ATTENTION : SHIP & STORE THIS SIDE UP

**HAND SANITIZER**  
ECO-DISPENSER

ATENCION : ENVIAR Y ALMACENAR ESTE LADO HACIA ARRIBA

ATTENTION : SHIP & STORE THIS SIDE UP

**HAND SANITIZER**  
ECO-DISPENSER

ATENCION : ENVIAR Y ALMACENAR ESTE LADO HACIA ARRIBA

PRODUCTO LIQUIDO 80% ALCOHOL/ALCOHOL

**CD** **3L** (94.5 FL OZ)

**SPRAY BOTTLES PACK**

EXTENSION DE VIDA DEL DISPENSADOR (844 IN USE)

**HAND SANITIZER**  
ECO-DISPENSER

INCLUYE 2 BOTELLAS RECARGABLES  
LLENA 12x BOTELLAS

**BOTELLAS**  
8.45 FL OZ

INSTRUCCIONES DE USO  
HOW TO USE THE HAND SANITIZER

www.cdhand sanitizer.com

**SPRAY BOTTLES PACK**

**HAND SANITIZER**  
ECO-DISPENSER

12x 8.45 FL OZ BOTTLES  
INSIDE THE BOX

LIQUID PRODUCT 80% ALCOHOL/ALCOHOL

**CD** **3L** (94.5 FL OZ)

**SPRAY BOTTLES PACK**

BASE IN ONE DISPENSER REFILL STATION  
BASE IN ONE DISPENSER REFILL STATION

**HAND SANITIZER**  
ECO-DISPENSER

INCLUYE 2 REFILLABLE BOTTLES  
FILL 12x BOTTLES

**BOTTLES**  
8.45 FL OZ

Topical Solution

www.cdhand sanitizer.com

**CD**

**SPRAY BOTTLES PACK**

**HAND SANITIZER**  
ECO-DISPENSER

12x 8.45 FL OZ BOTTLES  
INSIDE THE BOX

ATTENTION : PARA SERVIR MANTENGA ESTE LADO ARRIBA.

**HAND SANITIZER**  
ECO-DISPENSER

ADENTRO 2 BOTELLAS RECARGABLES  
ABRIR AQUI

ATTENTION : TO DISPENSE PUT THIS SIDE UP

**HAND SANITIZER**  
ECO-DISPENSER

2 EMPTY SPRAY BOTTLES INSIDE  
OPEN HERE

260 GAL NDC: 74336-180-04

750mL NDC: 74336-180-02

**LIQUID PRODUCT**

**CD**

**HAND SANITIZER ALCOHOL ANTISEPTIC**

**80%**

**750ML**

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

**DANGER**

**NON-POTABLE DO NOT DRINK**

**CD**

**HAND SANITIZER**  
**ALCOHOL ANTISEPTIC**  
TÓPICA SOLUCIÓN  
NON POTABLE SOLUTION  
750ML

Active Ingredient(s)	Purpose
Denatured Ethyl Alcohol 80% w/v	Antiseptic (antimicrobial)

**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, flush eyes thoroughly with water. Stop use and seek a doctor's visitation 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 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:** water, glycerin, hydrogen peroxide

Manufactured by: Caribbean Distillers, Carr. 173 Km 8.1 Cidra, P.R. 06739 Tel: 787-726-7100 License # 1136123904

**UPC CODE**

0 80896 00221 9

3000 mL NDC: 74336-180-01

**Borinquen CONTAINER CORPORATION**

Customer Name: Caribbean Distillers ID/PN: Hand Sanitizer 80% Date: 03/27/2020 Job #0901585

Style: D/C Size: 7+11/16 x 3+7/8 x 9+5/16 Blank Size: 17+11/16 x 24+7/8 Flute Test: B Flute ECT 32 Corr. Dir: Regular MPQ: Good In

Color 2 Color #1 Black GCM1 892 Color #2 Red GCM18 Color #3 None Color #4 None

Menstrado Para:  Flexo  Litografía  Rot. 65  .155  .250  Top  Bot  Surfwhite  Kraftboard **OUTSIDE VIEW** Drawing # 9853 B

**CD**

**HAND SANITIZER**  
**Alcohol Antiseptic 80%**  
**Topical Solution**

**CD**

**HAND SANITIZER**  
**Alcohol Antiséptico 80%**  
**Solución Tópica**

**3 L.**

**3 L.**

**3 L.**

**Image PRINTING PLATES**

Color Disclaimer: Due to the limitations of desktop scanners and the relative inconsistencies of various display monitors, the colors you see on your screen may not be a totally accurate reproduction of the actual product. We strive to make our colors as accurate as possible, but screen images are intended as a guide only and should not

18927 mL (5 gal.) 74336-180-03

**HAND SANITIZER**

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74336-180
<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	80 mL in 100 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:74336-180-01	3000 mL in 1 BAG; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74336-180-03	18927 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74336-180-02	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2020	
4	NDC:74336-180-04	984207 mL in 1 BAG; Type 0: Not a Combination Product	05/29/2020	
5	NDC:74336-180-05	3000 mL in 1 PACKAGE, COMBINATION; Type 1: Convenience Kit of Co-Package	05/25/2020	
6	NDC:74336-180-06	250 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	06/30/2020	

### 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	03/30/2020	

**Labeler** - Club Caribe LLC (117033117)

**Registrant** - Club Caribe LLC (117033117)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Club Caribe LLC		117033117	manufacture(74336-180)

