

HAND SANITIZER- alcohol liquid
Bearco 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.

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)

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.

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

Package Label - Principal Display Panel

250mL NDC 74331-180-05



3000ML FAMILY PACK NDC: 74331-180-05



260 GAL. NDC: 74331-180-04

<p>CD HAND SANITIZER Alcohol Antiseptic 80% Topical Solution Non-sterile Solution 3000 ml. (3L.)</p>	
Drug Facts	
Active ingredient[s]	Purpose
Denatured Ethyl Alcohol 80% v/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	
<ul style="list-style-type: none"> • 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 1 (800) 222-1222	
Directions	
<ul style="list-style-type: none"> • 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. 	
Other information	
<ul style="list-style-type: none"> • 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 Carr. 172 Km 9.1 Cidra, P.R. 00739 Tel: 787-739-7100	

750ML NDC: 74331-180-02

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
TOPICAL SOLUTION
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, rinse eyes thoroughly with water. Stop use and seek a doctor's attention 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. 179 Km 8.1 Cidra, P.R. 00739 Tel: 787-726-7100 License # 1136123904

UPC CODE

0 80896 00221 9

3000 mL NDC: 74331-180-01

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 Cor. Dir: Regular MPQ: 6000 in

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

Material: Flexo Latitud Rot. 65 Altura Sello: .155 .250 Top Rot Surfwhite Kraftboard **OUTSIDE VIEW** Drawing # 9853 B

CD

HAND SANITIZER
Alcohol Antiseptic 80%
Topical Solution

3 L.

HAND SANITIZER
80%
Alcohol Antiseptic

3 L.

HAND SANITIZER
Alcohol Antiséptico 80%
Solución Tópica

3 L.

Image PRINTING PLATES

Only 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

18927mL NDC: 74331-180-03

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74331-180
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)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74331-180-03	18927 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74331-180-01	3000 mL in 1 BAG; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74331-180-02	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2020	
4	NDC:74331-180-04	984207 mL in 1 BAG; Type 0: Not a Combination Product	05/29/2020	
5	NDC:74331-180-00	3000 mL in 1 PACKAGE, COMBINATION; Type 1: Convenience Kit of Co-Package	05/25/2020	
6	NDC:74331-180-05	250 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	06/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final	part333A	03/30/2020	
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Labeler - Bearco LLC (079308202)

Registrant - Bearco LLC (079308202)

Establishment			
Name	Address	ID/FEI	Business Operations
Bearco LLC		079308202	manufacture(74331-180)

Revised: 7/2020

Bearco LLC