

CALI DISTILLERY HAND SANITIZER- cali distillery hand sanitizer liquid

CALI Distillery

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

Drug Facts

Active ingredient

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- 30C (59- 86F)

- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

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.

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Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel



Alcohol Antiseptic 80%
Topical Solution Hand Sanitizer

Non-sterile Solution
External Use **Only**

Produced and Bottled by: **CALI Distillery** Gardena, CA
info@CaliDistillery.com

1 Gal NDC: 74500-0001-01



Alcohol Antiseptic 80%
Topical Solution Hand Sanitizer

Non-sterile Solution
External Use **Only**

A Product of **Medical Industries of the Americas**
For Emergencies Contact Chemtrec 1-800-424-9300

1 Gal NDC: 74500-0001-02

Drug Facts	
Active Ingredient	Purpose
Alcohol 80% v/v	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	
<ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds 	
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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	
<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 this product to avoid swallowing. 	
Other Information	
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Inactive Ingredients glycerin, hydrogen peroxide, purified water USP	



80% ALCOHOL
ANTISEPTIC SPRAY

HAND SANITIZER

NON-STERILE TOPICAL SOLUTION
EXTERNAL USE ONLY

Created for Amazon
by CALI Distillery

8oz / 237mL

We have turned our white whiskey into a powerful ethanol spray to keep you safe. We feel fortunate to help our community in these crazy times.

Spray on hands, surfaces or equipment and wait 30 seconds.

Be careful out there.

Harni & Howard
Founders, CALI Distillery
info@CaliDistillery.com

CALI Distillery
Gardena, CA

8 ounce NDC: 74500-0001-05

Drug Facts

Active Ingredient **Purpose**
Alcohol 80% v/vAntiseptic

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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Inactive Ingredients glycerin, hydrogen peroxide, purified water USP



80% ALCOHOL
ANTISEPTIC SPRAY

HAND SANITIZER

NON-STERILE TOPICAL SOLUTION
EXTERNAL USE ONLY

Created for Amazon
by CALI Distillery

16oz / 473mL

We have turned our white whiskey into a powerful ethanol spray to keep you safe. We feel fortunate to help our community in these crazy times.

Spray on hands, surfaces or equipment and wait 30 seconds.

Be careful out there.

Harni & Howard
Founders, CALI Distillery
info@CaliDistillery.com

CALI Distillery
Gardena, CA



1 Gal NDC: 74500-0001-04

CALI DISTILLERY HAND SANITIZER

cali distillery hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74500-0001
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: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74500-0001-2	18927 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74500-0001-1	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2020	
3	NDC:74500-0001-3	200000 mL in 1 DRUM; Type 0: Not a Combination Product	04/01/2020	
4	NDC:74500-0001-4	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2020	
5	NDC:74500-0001-5	946 mL in 1 BOTTLE, PLASTIC; 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 - CALIDistillery (091173262)

Establishment

Name	Address	ID/FEI	Business Operations
CALI Distillery		091173262	manufacture(74500-0001)

Revised: 5/2020

CALI Distillery