

CALI DISTILLERY GEL HAND SANITIZER- alcohol gel

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.

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) (70 to 72%, 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. Carbomer
- d. 85% triethanolamine
- e. Propylene glycol
- f. Sterile distilled water or boiled cold water.

Active Ingredient(s)

Alcohol 70% 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

- on 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, carbomer to gel, triethanolamine for PH balance, Propylene Glycol, Citrus oil, purified water USP

Package Label - Principal Display Panel

474 mL NDC: 74500-0004-1 front label



Antiseptic Hand Sanitizer

70% Ethanol

Gel Formulation with Essential Oils

Non-sterile Solution

External Use **Only**

16 OZ/ 474 ML

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

474 mL NDC: 74500-0004-1 back label

Drug Facts

Active Ingredient

Alcohol 70% 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.

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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, Carbomer, Triethanolamine, Propylene Glycol, Citrus Oil, Rosemary Oil, other Essential Oils, Water

Produced and Bottled by: **CALI Distillery Gardena, CA**

info@CaliDistillery.com

Made in the USA



1 gallon NDC: 74500-0004-5 front label



Antiseptic Hand Sanitizer
70% Ethanol

Gel Formulation with Essential Oils

Non-sterile Solution
External Use **Only**

32 oz label

Drug Facts	
Active Ingredient	Purpose
Alcohol 70% 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 • on 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, Carbomer, Triethanolamine, Propylene Glycol, Citrus Oil, Rosemary Oil, other Essential Oils, Water	



ANTISEPTIC HAND SANITIZER
70% ALCOHOL
GEL FORMULATION WITH ESSENTIAL OILS

HAND SANITIZER GEL

NON-STERILE TOPICAL SOLUTION
EXTERNAL USE ONLY

32oz / 946mL

Our Sanitizer is double-distilled from American Corn into pure 200 proof alcohol and then blended to create a "skin friendly" gel to keep you safe and your hands comfortable.

We feel fortunate to help our community in these crazy times.

Rub on your hands until dry.

Be careful out there.

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

CALI Distillery
Gardena, CA
Made in the USA



gallon NDC: 74500-0004-5 back label

Drug Facts

Active Ingredient

70% alc 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

remade 8 ounce

Drug Facts

Active ingredient(s)	Purpose
Alcohol 70% w/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.

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Do not use • on 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.
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Other information

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

Inactive ingredients

Water (Aqua, Eau), Glycerin, Carbomer, Propylene Glycol, Squalane, Fragrance (Parfum), Aloe Barbadensis Leaf Juice, Tocopheryl Acetate.

ReMadeUSA®

Antiseptic Hand Sanitizer
70% Alcohol



Gel Hand Sanitizer

Non Sterile Topical Solution
External use ONLY
8oz / 237mL

Our sanitizer is double distilled from American Corn into pure 200 proof alcohol and then blended to create a 'skin friendly' gel to keep you safe and your hands comfortable.

ReMadeUSA®

sales@remade.us

ReMade USA
Los Angeles, CA



Made in USA, Veteran Owned

Drug Facts

Active Ingredient	Purpose
Alcohol 70% w/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

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Do not use

- on 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 and pets. 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, Carbomer, Triethanolamine, Propylene Glycol, Citrus Oil, Rosemary Oil, other Essential Oils, Water

spectrum®
CHEMICAL MFG CORP

Hand Sanitizer Gel



Antiseptic Hand Sanitizer
Gel Formulation with Essential Oils
Non-Sterile Topical Solution
External Use Only

Quality Ingredients for 50 Years

Spectrum manufactures and distributes the largest offering of USP chemicals in the world, including laboratory, scale up and bulk quantities. We provide fine chemicals, equipment and supplies to a wide range of industries such as pharmaceutical, biopharm, personal care & cosmetics, food & beverage, pharmacy compounding, and more. Our bicoastal cGMP facilities are FDA registered and inspected, with additional certification to the ISO 9001:2015 standard.

SpectrumChemical.com
800.772.8786

Made in the USA 

Catalog No. HS70G
Lot: GL7008 201215
Distributed by Spectrum Chemical Mfg. Corp.

8 OZ / 237 mL

ReMadeUSA®



**ANTISEPTIC HAND SANITIZER
70% Alcohol**



**GEL
HAND
SANITIZER**

128 FL OZ

Drug Facts	
Active ingredient(s) Alcohol 70% v/v	Purpose Antiseptic
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Warnings	
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Do not use on children less than 2 months of age on open skin wounds	
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Inactive ingredients	
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ReMade USA
Los Angeles, CA

Download MSDS



NON STERILE TOPICAL SOLUTION
EXTERNAL USE ONLY



Made in USA, Veteran Owned

CALI DISTILLERY GEL HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74500-0004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	2 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.1 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74500-0004-1	474 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74500-0004-2	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74500-0004-3	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74500-0004-4	1893 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
5	NDC:74500-0004-5	3786 mL in 1 BOTTLE, PUMP; 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 - CALI Distillery (091173262)

Establishment

Name	Address	ID/FEI	Business Operations
Cali Distillery		091173262	manufacture(74500-0004)

Revised: 1/2022

CALI Distillery