

HAND SANITIZER- alcohol liquid
Elevated Mountain Distilling Company

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[s] Alcohol 80% v/v.....	PurposeAntiseptic
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.	
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 <ul style="list-style-type: none">• 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

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Inactive ingredients

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Package Label - Principal Display Panel

1892 mL NDC: 74273-002-00



HAND SANITIZER Topical Solution

**ALCOHOL ANTISEPTIC
Non-Potable Solution**

80%

1 Gallon(3,785.41 ml)

Denatured alcohol by adding 5% Isopropyl Alcohol.
Ethanol 80% as determined by densimeter reading. For use in
production of hand sanitizers. Antiseptic hand rub only.

Manufactured By:

Elevated Mountain Distilling Co.
3732 Soco Road, Maggie Valley, NC 28751

(828) 944-0766 dangell@elevatedmountain.com

Manufacturer FDA# (DUNS): 058858464

Manufactured on March 31, 2020

Released on April 2, 2020

Batch #1

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74273-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	1577 mL in 1892 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	27.5 mL in 1892 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	79 mL in 1892 mL
WATER (UNII: 059QF0K00R)	209 mL in 1892 mL

Packaging

	Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74273-002-00	1892 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 - Elevated Mountain Distilling Company (058858464)

Establishment			
Name	Address	ID/FEI	Business Operations
Elevated Mountain Management Group		058858464	manufacture(74273-002)

Revised: 4/2020

Elevated Mountain Distilling Company