

HAND SANITIZER- alcohol solution
Chervona, 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.

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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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

The image shows the principal display panel of a Mammoth Holistics Hand Sanitizer package. The design is dark blue with white and orange text. The logo features a mountain peak with a cannabis leaf inside a shield, above the text 'MAMMOTH HOLISTICS YOUR CANNABIS STORE'. Below this, it says 'HAND SANITIZER' and '80% ALCOHOL ANTISEPTIC TOPICAL NON-STERILE SOLUTION'. A paragraph describes the brand's mission: 'Elevating and educating our community as Mammoth's leading provider of safe, premium quality and sustainably-sourced cannabis for medical and recreational use.' It also mentions a 'special edition supporting our customers & community'. At the bottom, it lists '2 fl oz | 59 mL' and 'C10-0000617-LIC'. To the right is a white box containing a 'Drug Facts' table for 'Liquid Spray Sanitizer'. The table lists the active ingredient as Ethyl Alcohol 80% w/v, with an antiseptic purpose. It includes sections for Use(s), Warnings (external use only, flammable), Do not use (children under 2, open wounds), When using (avoid eyes), Stop use (irritation), Keep out of reach of children, Directions (rub hands, supervise children), and Other Information (storage, freezing avoidance). Inactive ingredients are listed as glycerin, hydrogen peroxide, and purified water USP. The Mammoth Holistics logo and website are at the bottom of the white box, along with manufacturer information: 'Manufactured by CHERVONA Vodka, www.chervonavodka.com, Made in the U.S.A.'

MAMMOTH HOLISTICS
YOUR CANNABIS STORE

HAND SANITIZER
80% ALCOHOL ANTISEPTIC TOPICAL NON-STERILE SOLUTION

Elevating and educating our community as Mammoth's leading provider of safe, premium quality and sustainably-sourced cannabis for medical and recreational use.

special edition
supporting our customers & community

2 fl oz | 59 mL
C10-0000617-LIC

Liquid Spray Sanitizer

Drug Facts	
Active ingredient(s) Ethyl Alcohol 80% w/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 <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	

MAMMOTH HOLISTICS
YOUR CANNABIS STORE

MAMMOTHHOLISTICS.COM
Manufactured by CHERVONA Vodka
www.chervonavodka.com
Made in the U.S.A.

59 mL NDC: 80367-003-01

HAND SANITIZER

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80367-003
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)	18.415 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80367-003-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/15/2020	

Labeler - Chervona, LLC (090741316)

Registrant - Chervona, LLC (090741316)

Establishment

Name	Address	ID/FEI	Business Operations
Chervona, LLC		090741316	relabel(80367-003) , repack(80367-003) , manufacture(80367-003)

Revised: 12/2020

Chervona, LLC