

HAND SANITIZER- alcohol liquid

A Natural Clean, 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.

80 % Ethanol Peppermint Mist with Aloe

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.

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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



ADVANCED FORMULA
Hand Sanitizer
Soothing Peppermint Mist



1 FL OZ (29mL)

HSMA-P1-1F

Drug Facts	
Active Ingredient(s)	Purpose
Ethyl alcohol 80% v/v.....	Antimicrobial
Use(s)	
Hand sanitizer to help reduce bacteria on the skin.	
Warnings	
Flammable. Keep away from fire 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.	

Drug Facts (continued)	
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 below 43C (100F)	
Inactive ingredients	
purified water(aqua), glycerin, hydrogen peroxide, aloe barbadensis leaf juice, peppermint oil	

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Drug Facts

Active ingredient(s)	Purpose
Echinacea extract (Echinacea purpurea)	Antimicrobial

Warnings
Flammable. Keep away from fire or flame. For external use only.

Safety Do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and persists.

Keep Out of reach of children. If swallowed, contact a Poison Control Center.

Handling: Store below 110°F (43°C).

Inactive Ingredients: Water/Aqua, Glycerin, Isopropyl Alcohol, Aloe, Salvia officinalis Leaf Juice, Peppermint Oil.

Distributed by:
A Natural Clean
Henderson, NY 11801
Made in the USA
www.anaturalcleanliving.com



HAND SANITIZER

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77124-004
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)			2.05 mL in 100 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
WATER (UNII: 059QF0K00R)			17.75 mL in 100 mL	
ALOE VERA LEAF (UNII: ZY81Z83H0X)			0.075 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77124-004-01	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2020	
2	NDC:77124-004-02	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2020	
3	NDC:77124-004-03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	06/05/2020	

Labeler - A Natural Clean, LLC (117509697)

Revised: 5/2020

A Natural Clean, LLC