

HAND SANITIZER- alcohol jelly
ALFA VITAMINS LABORATORIES INC

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 70% v/v. Purpose: Antiseptic

Active ingredient

Ethyl Alcohol 70% v/v.....

Purpose

Antiseptic, Hand Sanitizer

Purpose

.....**Antiseptic**

DIRECTIONS

Place enough product in your to thoroughly cover hands

Rub hands together briskly until mdry

Children under 6 years of age should be supervised when using the product

Directions

- Place enough product in your palm to thoroughly cover hands
- Rub hands together briskly until dry
- Children under 6 years of age should be supervised when using this product

Warnings

For external use only. Flammable. Keep away from heat or flame

Warnings

Flammable. Keep away from fire or flame.

Do not use

- Do not get into eyes
- If contact occurs, rinse eyes thoroughly with water

When use this product

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Irritation or rash appears and lasts

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Other information

- Store below 110F (43C)
- May discolor certain fabrics or surfaces

Other Information

- Store below 110° F (43° C)
- May discolor certain fabrics or surfaces

Inactive ingredients

Aloe Vera, Carbomer, Fragrance, Glycerin, Methyl Gluceth-20, Purified Water, Propylene Glycol, Triethanolamine

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Package Label - Principal Display Panel

472 mL NDC: 13298-156-16





**70%
ALCOHOL**



INSTANT

Hand Sanitizer

**With
Aloe**



KILLS 99.9% OF GERMS

16 FL Oz (472 mL)

HAND SANITIZER

alcohol jelly

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13298-156
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	99.8 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0K00R)	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	99 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	99 mL in 100 mL
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	99 mL in 100 mL
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)	25 mL in 100 mL
TRIETHANOLAMINE DODECYLBENZENESULFONATE (UNII: 8HM7ZD48HN)	99 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13298-156-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:13298-156-16	472 mL in 1 BOTTLE; 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 - ALFA VITAMINS LABORATORIES INC (120728212)

Registrant - ALFA VITAMINS LABORATORIES INC (120728212)

Establishment

Name	Address	ID/FEI	Business Operations
ALFA VITAMINS LABORATORIES INC		120728212	manufacture(13298-156) , pack(13298-156) , label(13298-156)