## HAND SANITIZER- alcohol gel Laboratoires Colba 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.

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## Alpen Secrets Antiseptic Hand Cleanser

## **Active Ingredient(s)**

Alcohol 75% 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.

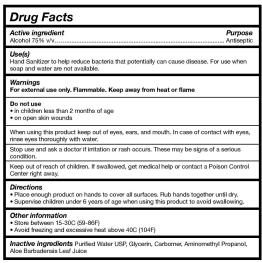
### Other information

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

### **Inactive ingredients**

Purified Water USP, Glycerin, Carbomer, Aminomethyl Propanol, Aloe Barbadensis Leaf Juice

### Package Label - Principal Display Panel

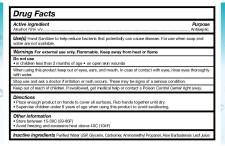




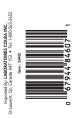


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Drug Facts

Active ingredient Alcohol 75% v/v.....

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# HAND SANITIZER

alcohol gel

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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77431-075
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Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

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

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	0.1 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	23.4 mL in 100 mL
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	0.35 mL in 100 mL

AMINOMETHYLPROPANOL (UNII: LU49E6626Q)
0.15 mL in 100 mL

# Packaging

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	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:77431-075- 01	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	
l	2 NDC:77431-075- 05	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/18/2020	
	3 NDC:77431-075- 10	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/18/2020	

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/18/2020	

# Labeler - Laboratoires Colba inc. (245165907)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
laboratoires Colba inc.		245165907	manufacture(77431-075)	

Revised: 6/2020 Laboratoires Colba inc.