# ELASKIN ANTISEPTIC HAND SANITIZER- is opropyl alcohol solution Aleo BME, 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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#### IPA 75% Antiseptic Topic Solution, Hand Sanitizer

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. Isopropyl Alcohol (75%, 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)

Isopropyl 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

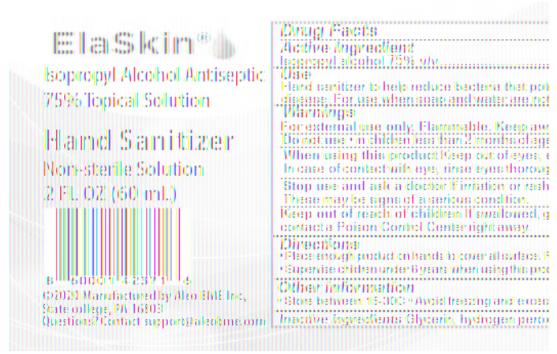
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

#### **Inactive ingredients**

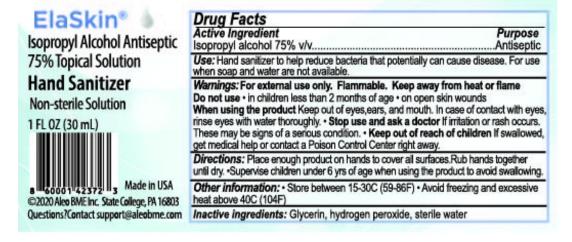
glycerin, hydrogen peroxide, sterile water

#### Package Label - Principal Display Panel

60 mL NDC: 74533-003-02



30mL NDC: 74533-003-01



# ElaSkin® (

Isopropyl Alcohol Antiseptic 75% Topical Solution

### **Hand Sanitizer**

4 FL OZ (118 mL)



Made in USA ©2020 by Aleo BME Inc. State college, PA 16803

### Drug Facts

Active Ingredient Isopropyl alcohol 75% v/v...

Purpose .Antiseptic

Use Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

#### Warnings

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When using this product Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water

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

#### 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

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

Questions? Contact support@aleobme.com Inactive ingredients Glycerin, hydrogen peroxide, sterile water

950 mL NDC: 74533-003-04



Isopropyl Alcohol Antiseptic 75% Topical Solution

# Hand Sanitizer Refill

32 FL OZ (950 mL)



Made in USA ©2020 by Aleo BME Inc. State college, PA 16803 Questions? Contact support@aleobme.com

### Drug Facts

Active Ingredient Purpose Isopropyl alcohol 75% v/v......Antiseptic

#### 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.

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

#### 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

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

Inactive ingredients Glycerin, hydrogen peroxide, sterile water

#### ELASKIN ANTISEPTIC HAND SANITIZER

isopropyl alcohol solution

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:74533-003

Route of Administration TOPICAL

#### Active Ingredient/Active Moietv

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Ingredient Name	Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74533-003- 02	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/02/2020	
2	NDC:74533-003- 01	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/02/2020	
3	NDC:74533-003- 03	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/04/2020	
4	NDC:74533-003- 04	950 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/02/2020		

## **Labeler** - Aleo BME, Inc. (079856690)

Establishment			
Name	Address	ID/FEI	Business Operations
Aleo BME, Inc.		079856690	manufacture(74533-003)

Revised: 5/2020 Aleo BME, Inc.