

ALCOHOL 80% TOPICAL ANTISEPTIC, HAND SANITIZER- alcohol liquid

Pisgah Labs, 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.

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. 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

80 % Alcohol

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution



3222 Old Hendersonville Hwy, Pisgah Forest, NC 28768
Phone: (828) 884-2789, Fax: (828) 484-4614

32oz (946mL)

**Manufactured in an FDA Registered
GMP Facility**

<i>Drug Facts</i>	
<i>Active ingredient[s]</i>	<i>Purpose</i>
Alcohol 80% v/v	Antiseptic
<i>Use[s]</i>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<i>Warnings</i>	
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Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)	
<i>Inactive ingredients</i>	
glycerin, hydrogen peroxide, purified water USP	
Code 128 Barcode	

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution



PISGAH LABS, inc.

3222 Old Hendersonville Hwy, Pisgah Forest, NC 28768
Phone: (828) 884-2789, Fax: (828) 484-4614

16oz (473mL)

**Manufactured in an FDA Registered
GMP Facility**

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic
Use[s]	
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Warnings	
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Inactive ingredients	
glycerin, hydrogen peroxide, purified water USP	
Code 128 Barcode	

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution



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3222 Old Hendersonville Hwy, Pisgah Forest, NC 28768
Phone: (828) 884-2789, Fax: (828) 484-4614

12oz (355mL)

**Manufactured in an FDA Registered
GMP Facility**

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic
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Inactive ingredients	
glycerin, hydrogen peroxide, purified water USP	
Code 128 Barcode	

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution



PISGAH LABS, inc.

3222 Old Hendersonville Hwy, Pisgah Forest, NC 28768
Phone: (828) 884-2789, Fax: (828) 484-4614

8oz (237mL) Squeeze Bottle

**Manufactured in an FDA Registered
GMP Facility**

Drug Facts

Active ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic

Use[s]

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Code 128 Barcode

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution



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3222 Old Hendersonville Hwy, Pisgah Forest, NC 28768
Phone: (828) 884-2789, Fax: (828) 484-4614

8oz (237mL)

**Manufactured in an FDA Registered
GMP Facility**

Drug Facts

Active ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic

Use[s]

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Code 128 Barcode

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution

 **PISGAH LABS, inc.**
3222 Old Hendersonville Hwy, Pisgah Forest, NC 28768
Phone: (828) 884-2789, Fax: (828) 484-4614

4oz (118mL) Squeeze Bottle

**Manufactured in an FDA Registered
GMP Facility**

Drug Facts

Active ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic

Use[s]

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Code 128 Barcode

ALCOHOL 80% TOPICAL ANTISEPTIC, HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63804-6000
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)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63804-6000-5	118 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
2	NDC:63804-6000-2	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:63804-6000-3	237 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
4	NDC:63804-6000-1	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:63804-6000-4	473 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
6	NDC:63804-6000-6	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Alcohol Antiseptic 80% Topical Solution

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Phone: (828) 884-2789, Fax: (828) 484-4614

1 US Gallon (128floz (3785mL))**Manufactured in an FDA Registered
GMP Facility****Drug Facts**

Active ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic

Use[s]

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Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Code 128 Barcode

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Pisgah Labs, Inc (105807127)

Registrant - Pisgah Laboratories, Inc (105807127)

Establishment

Name	Address	ID/FEI	Business Operations
Pisgah Laboratories, Inc		105807127	manufacture(63804-6000)

Revised: 4/2020

Pisgah Labs, Inc