HAND SANITIZER- alcohol liquid AVAPCO 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.

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.

*Or equivalent grades according to the to the United States Pharmacopeia's guidance "Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic."

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, boiled water

Package Label - Principal Display Panel



hand sanitizer

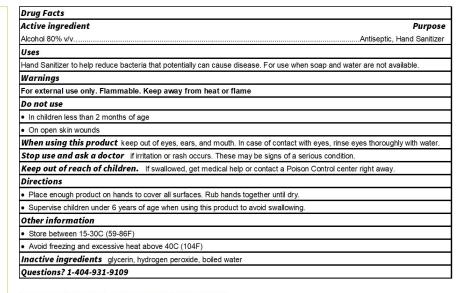
Alcohol Antiseptic 80% Topical Solution Non-sterile solution

Contents: Alcohol (ethanol) (80%, volume/volume (v/v)) in an aqueous solution denatured according to TTB regulations in 27 CFR part 20, Glycerol (1.45% v/v), Hydrogen peroxide (0.125% v/v), Boiled water

This product is manufactured according to World Health Organization (WHO) recommendations and the FDA's Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoVID-19); Guidance for Industry.

The product is manufactured using United States Pharmacopoeia (USP) grade ingredients or equivalent grades according to the to the United States Pharmacopeia's "Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic."

(3.8 L, Registered FDA National Drug Code 74383-1234-5)



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Manufactured by AVAPCO LLC, a subsidiary of GranBio Technlogies, Thomaston, GA, 30286 Made in U.S.A

Expiraton Date:



hand sanitizer

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(3.8 L, Registered FDA National Drug Code 74383-1234-1)

Drug Facts

Active ingredient Purpose

Uses

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Questions? 1-404-931-9109

Registered FDA National Drug Code 74383-1234-1

Manufactured by AVAPCO LLC, a subsidiary of GranBio Technologies, Thomaston, GA, 30286 Made in U.S.A

Expiration Date:

3.8L NDC: 74383-1234-1 208 L NDC: 74383-1234-5

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74383-1234
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Route of Administration TOPICAL

	Active	Ingred	lie nt/ <i>E</i>	\ctive	Moiety
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	Ingredient Name	Basis of Strength	Strength
ALC	OHOL (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
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

]	Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:74383-1234-1	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2020		
2	NDC:74383-1234-5	208198 mL in 1 DRUM; Type 0: Not a Combination Product	03/31/2020		

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

Labeler - AVAPCO LLC (039024119)

Registrant - AVAPCO LLC (039024119)

Establishment				
Name	Address	ID/FEI	Business Operations	
AVAPCO LLC		039024119	manufacture(74383-1234)	

Revised: 3/2020 AVAPCO LLC