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

GranBio

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)

Drug Facts	
Active ingredient	***Purpose***
Alcohol 80% v/v.....	Antiseptic, Hand Sanitizer
Uses	
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Inactive ingredients glycerin, hydrogen peroxide, boiled water	
Questions? 1-404-931-9109	

Registered FDA National Drug Code 74383-1234-5

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

Expiraton Date:

GranBio

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

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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 74383-1234-1)

Drug Facts
Active ingredient **Purpose**
Alcohol 80% v/v.....Antiseptic, Hand Sanitizer
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Inactive ingredients glycerin, hydrogen peroxide, boiled water
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

Expiraton 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
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: 059QF0KO0R)	

Packaging

#	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