# HEMPTUARY HAWAII HAND SANITIZER- isopropyl alcohol liquid Aloha Green Holdings 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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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

Flammable. Keep away from heat or flam. For external use only.

#### 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.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

### **Directions**

- Apply product onto hands, spread thoroughly, cover all surfaces, and rub hands until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

### Other information

- Store between 59-86F
- Avoid freezing and excessive heat above 104F

# **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

3785 ml NDC: 73999-002-01



# HEMPTUARY

HAWAII

# Hand Sanitizer

Isopropyl Alcohol Antiseptic 75%

Topical, Non-Sterile Solution

1 Gallon: 3785ml

# Handcrafted in Honolulu, Hawaii

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

## Stay Healthy Hawaii!



#### DIRECTIONS

Apply product onto hands, spread thoroughly, cover all surfaces, and rub until dry. Supervise children under 6 year of age when using this product to avoid swallowing.

#### Drug Facts:

Active Ingredients..Purpose Isopropyl Alcohol 75% v/v Antiseptic

Inactive Ingredients: glycerin, hydrogen peroxide, purified water USP

Other information: Store between 59-86F. Avoid freezing and excessive heat above 104F.

Warnings: Flammable. Keep away from heat or flame. For external use only. Do not ingest. If swallowed, get medical help or contact a Poison Control Center right away. Keep out of reach of children. Do not use for children less than 2 months of age or on open 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.

Made by Aloha Green Holdings Inc NDC 73999-002-1 for:

# Hemptuary

2113 Kalakaua Ave (808) 824-HEMP HemptuaryHawaii.com

# **HEMPTUARY HAWAII HAND SANITIZER**

isopropyl alcohol liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73999-002

**Route of Administration** TOPICAL

### **Active Ingredient/Active Moiety**

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
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:73999- 002-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/01/2020		

# Labeler - Aloha Green Holdings Inc. (117302715)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Aloha Green Holdings Inc.		117302715	manufacture(73999-002)	

Revised: 1/2022 Aloha Green Holdings Inc.