HAND SANITIZER- isopropyl alcohol gel
Lokahi Brewing Company 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

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients.

a. Isopropyl Alcohol (70%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
b. Glycerin (4% v/v).
c. Hydroxyethylcellulose (1.5% v/v).
d. Aloe Barbadensis Leaf Juice (0.5% v/v).
e. 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 70% 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
- in open cuts or 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.

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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, hydroxyethyl cellulose, Aloa Barbadensis, purified water USP

Package Label - Principal Display Panel

60 ml NDC: 78240-001-01

LOKAHI
BREWING COMPANY

HAND SANITIZER

Active Ingredient Isopropyl Alcohol 70%....Antiseptic
Uses Hand Sanitizer to decrease bacteria on the skin that can potentially cause disease.
Warning For External Use Only. Flammable. Keep away from heat or flame
Do not use on children less than 2 months of age. in open cuts or 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.
Directions of Use Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under the age of 6 years in the use of this product.
Store between 59-86F(15-30C) Avoid freezing and excessive heat above 104F(40C)
Inactive ingredients Water, Glycerin, Hydroxyethylcellulose, Aloe Barbadensis Leaf Juice

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HAND SANITIZER
isopropyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78240-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	42 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE ANDONGENSIS LEAF (UNII: N1P4NU25EJ)	0.3 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	2.4 mL in 100 mL
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	0.9 mL in 100 mL
WATER (UNII: 059QF0KO0R)	24 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78240-001-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

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

Labeler - Lokahi Brewing Company LLC (122458275)

Establishment

Name	Address	ID/FEI	Business Operations
Lokahi Brewing Company LLC		122458275	manufacture(78240-001)

Revised: 6/2020 Lokahi Brewing Company LLC