PIPERWAIHANDSANITIZERLEMONGRASS- alcohol solution Piperwai, 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.

This is a hand rub manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Rub Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand rub 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) (62%,) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol
- c. Sterile distilled water.

Active Ingredient(s)

Ethyl Alcohol 62%. Purpose: Antiseptic

Purpose

Antiseptic, Hand Rub

Use

Reduces the amount of bacteria on hands. Recommended for repeated use.

Warnings

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

Do not use

- aviod contact with eyes.
- In case of contact, flush thoroughly with water.

When using this product aviod contact with eyes. In case of contact, flush thoroughly with water.

Stop use and ask a doctor if irritation occurs.

Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Pump onto dry hands as needed coating evenly.
- Allow to dry without wiping
- Supervise children under 6 years old
- Not recommended for infants.

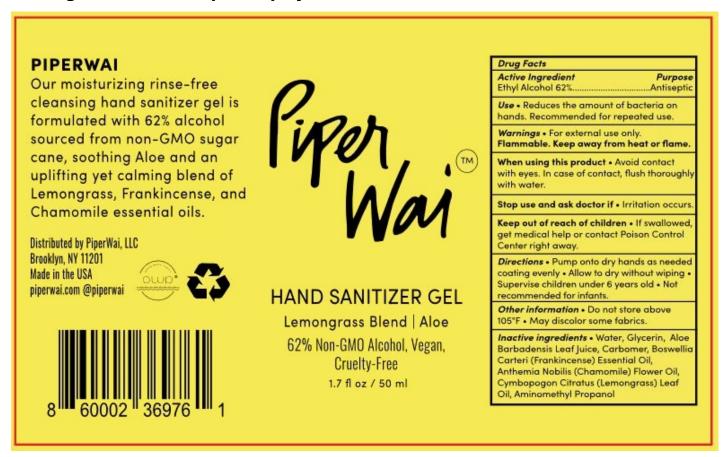
Other information

Do not store above 105F

Inactive ingredients

Water, Glycerin, Aloe Barbadensis Leaf Juice, Carbomer, Rosmarinus Officinalis (Rosemary) Leaf Oil, Mentha Piperita (Peppermint) Oil, Aminomethyl Propanol

Package Label - Principal Display Panel



PIPERWAIHANDSANITIZERLEMONGRASS

alcohol solution

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:81741-110

TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
FRANKINCENSE OIL (UNII: 67ZYA5T02K)				
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)				
JAMMU LEMONGRASS OIL (UNII: K25ZLU1I0O)				
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)				
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)				
GLYCERIN (UNII: PDC6A3C0OX)				
aloe (UNII: V5VD430YW9)				
WATER (UNII: 059QF0KO0R)				

Packaging

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	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		NDC:81741-110- 01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2021		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/31/2021	

Labeler - Piperwai, LLC (047558690)

Registrant - Cospro Development Corp (785638821)

Establishment				
Name	Address	ID/FEI	Business Operations	
Cospro Development Corp		785638821	manufacture(81741-110) nack(81741-110) label(81741-110)	

Revised: 3/2021 Piperwai, LLC