ORIGINAL HAND SANITIZER GEL FIG RHUBARB- isopropyl alcohol 70% v/v gel Pame Eco Technology 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.

Original Hand Sanitizer Fig Rhubarb 70% IPA gel

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:

- 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.

Active Ingredient(s)

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
- 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

Water, Glycerin, Castor Seed Oil, Isopropyl Myristate, Acrylates Copolymer, Aloe Vera Juice, Tocopheryl Acetate, Triethanolamine, Fragrance.

Package Label - Principal Display Panel

500 mL NDC: 81451-143-05



ORIGINAL HAND SANITIZER GEL FIG RHUBARB

isopropyl alcohol 70% v/v gel

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:8	NDC:81451-143	
Route of Administration	TOPICAL					
Active Ingredient/Active	Moiety					
Ing	redient Name		Basis of Strengtl	-	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - ISOPROPYL ALCOHOL - UNII: ND2M416302)				-	70 mL in 100 mL	
Inactive Ingredients						
Ingredient Name				9	Strength	
ACRYLATES CROSSPOLYMER-6	(UNII: 4GXD0Q3OS3)					
ALOE VERA LEAF (UNII: ZY81Z83	3H0X)					
.ALPHATOCOPHEROL ACETAT	E (UNII: 9E8X80D2L0)					
GLYCERIN (UNII: PDC6A3C0OX)						
TROLAMINE (UNII: 903K93S3TK)						
WATER (UNII: 059QF0KO0R)						

ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)

CASTOR OIL (UNII: D5340Y2I9G)

Packaging Marketing Start **Marketing End** # Item Code **Package Description** Date Date 1 NDC:81451-143-05 500 mL in 1 BOTTLE; Type 0: Not a Combination Product 08/25/2021 **Marketing Information Application Number or Monograph** Marketing End Marketing Marketing Start Category Citation Date Date OTC monograph not part333A 08/25/2021 final

Labeler - Pame Eco Technology Inc (204258441)

Registrant - Pame Eco Technology Inc (204258441)

Establishment			
Name	Address	ID/FEI	Business Operations
Pame Eco Technology Inc		204258441	manufacture(81451-143)

Revised: 8/2021

Pame Eco Technology Inc