ORIGINAL HAND SANITIZER CEDAR FOREST- alcohol 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.

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.

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.

Package Label - Principal Display Panel

100 mL NDC: 81451-111-01



DRUG FACTS / INFO-MÉDICAMENT

ACTIVE INGREDIENT: ETHYL ALCOHOL 70% V/V INGRÉDIENT ACTIF: ETHYL ALCOHOL 70% V/V USES: EFFECTIVE IN DESTROYING (HARMFUL) BACTERIA TO PROVIDE ANTISEPTIC CLEANSING. RECOMMENDED FOR REPEATED USE. UTILISATIONS: EFFECTIF POUR DÉTRUIRE LES BACTÉRIES (NOCIVES) POUR FOURNIR UN NETTOYAGE ANTISEPTIQUE. RECOMMANDÉ POUR UN USAGE RÉPÉTÉ. WARNINGS: FLAMMABLE -KEEP AWAY FROM FIRE OR FLAME. AVERTISSEMENTS: INFLAMMABLE: GARDER ÉLOIGNÉ DU FEU OU DES FLAMMES. *FOR EXTERNAL USE ONLY* *POUR UN USAGE EXTRENE UNIQUEMENT* WHEN USING THIS PRODUCT AVOID CONTACT WITH EYES. IF CONTACT OCCURS. RINSE THOROUGHLY WITH WATER. STOP USE AND ASK A DOCTOR IF RASH OR IRRITATION DEVELOPS AND LASTS FOR MORE THAN 72 HOURS. NE PAS METTRE DANS LES YEUZ EN CAS DE CONTACT AVEC LES YEUX, LES RINCER À L'EAU. ARRÊTER L'UTILISATION ET CONSULTER UN DOCTEUR SI UNE IRRITATION OU UNE ROUGEUR SE DÉVELOPPE ET DURE PLUS DE 72 HEURES. KEEP OUT OF REACH OF CHILDREN: IF SWALLOWED, CALL A POISON CONTROL CENTRE OR MEDICAL HELP RIGHT AWAY. GARDER HORS DE LA PORTÉE DES ENFANTS: EN CAS D'INGESTION, CONSULTEZ UN MÉDECIN OU UN CENTRE ANTIPOISON. DIRECTIONS: RUB THOROUGHLY INTO HANDS FOR AT LEAST 30 SECONDS. ALLOW TO DRY, FOR CHILDREN UNDER 6, USE ONLY UNDER ADULT SUPERVISION. NOT RECOMMENDED FOR INFANTS. MODE D'EMPLOI: FROTTER VIVEMENT VOS MAIN ENSEMBLE POUR 30 SECONDES. PUIS LAISSER SÉCHER À L'AIR. POUR LES ENFANTS DONT L'ÂGE EST INFÉRIEUR À 6 ANS, UTILISER LE PRODUIT SOUS LA SUPERVISION D'UN ADULTE. NON RECOMMANDÉ POUR LES NOURRISSONS. OTHER INFORMATION: DO NOT STORE ABOVE 105F (41C). AUTRE INFORMATION: ENTREPOSER À DES TEMPÉRATURES INFÉRIEURES À

INACTIVE INGREDIENTS /INGRÉDIENTS INACTIFS: AQUA (WATER/EAU), RICINUS COMMUNIS (CASTOR) SEED OIL, ACRYLATES COPOLYMER, GLYCERIN, ALOE VERA JUICE, ISOPROPYL MYRISTATE, TOCOPHERYL ACETATE, TRIETHANOLAMINE, PARFUM (FRAGRANCE).

PAME ECO TECHNOLOGY INC. 86B NORTHLINE ROAD, TORONTO ON, M4B 3E5, CANADA TOLL-FREE / SANS FRAIS: 1 (833) 726-3326

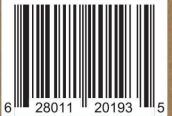
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MADE IN CANADA FABRIQUÉ AU CANADA

RECYCLE RECYCLER

Strength



ORIGINAL HAND SANITIZER CEDAR FOREST

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:81451-111

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)
ALCOHOL (UNII: 3K9958V90M) ALCOHOL 70 mL in 100 mL

Ingredient Name ACRYLATES CROSSPOLYMER-6 (UNII: 4GXD0Q3OS3) ALOE VERA LEAF (UNII: ZY81Z83H0X)

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
GLYCERIN (UNII: PDC6A3C0OX)

TROLAMINE (UNII: 903K93S3TK)
WATER (UNII: 059QF0K00R)

Inactive Ingredients

ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)

CASTOR OIL (UNII: D5340Y2I9G)

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:81451-111- 01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/18/2021				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	02/18/2021				

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(81451-111)					

Revised: 2/2021 Pame Eco Technology Inc