

ORIGINAL HAND SANITIZER MYSTIC OUD- ethyl 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 Mystic Oud 500 ml ethyl alcohol 70% v/v

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, Fragrance.

Package Label - Principal Display Panel

PÁMECARE®

DELUXE
HAND SANITIZER GEL
GEL DÉSINFECTANT
POUR LES MAINS DE LUX

MYSTIC OUD
MYSTIQUE OUD

MOISTURIZES HANDS / HYDRATE LES MAINS
NON-TACKY / NON-COLLANT
GENTLE ON HANDS / DOUX SUR LES MAINS
SMELLS GREAT / ÇA SENT BON

ALOE VERA / ALOË VERA
GLYCERIN / GLYCÉRINE
CASTOR OIL / HUILE DE CASTOR
VITAMIN E / VITAMINE E

500 ML
(16.9 FL. OZ.)
POWERED BY / ALIMENTÉ PAR
MANOFESTING

PÁMECARE® +
HAND SANITIZER GEL
GEL DÉSINFECTANT POUR LES MAINS

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: EFFICACE POUR DÉTRUIRE LES BACTÉRIES
(NOUVELES) 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 EXTÉRIEUR 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 YEUX 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
ANTIPHOISON. **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 MAINS ENSEMBLE POUR 30 SECONDES, PLUS
LASSER 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 (40C). AUTRE
INFORMATION: ENTREPOSER À DES
TEMPÉRATURES INFÉRIEURES À 105F
(40C). **INACTIVE INGREDIENTS/**
INGRÉDIENTS INACTIFS: AQUA
(WATER/EAU), RICINUS COMMUNIS
(CASTOR SEED OIL, ACRYLATES
COPOLYMER, GLYCERIN, ALOE VERA
JUICE, ISOPROPYL MYRISTATE,
TOCOPHERYL ACETATE, TRIETHANOL-
AMINE, PARFUM (FRAGRANCE).

PÁMECARE

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NPN 80107893

6 280112 011178

500 ml NDC: 81451-125-05

ORIGINAL HAND SANITIZER MYSTIC OUD

ethyl alcohol 70% v/v gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81451-125
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ACRYLATES CROSSPOLYMER-6 (UNII: 4GXD0Q30S3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CASTOR OIL (UNII: D5340Y219G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81451-125-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/09/2021	

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(81451-125)

Revised: 3/2021

Pame Eco Technology Inc