

HAND SANITIZER ROYAL OUD- isopropyl alcohol 70% v/v gel
Pame Eco Tech

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.

Pame Care Deluxe: Royal Oud Hand Sanitizer Gel

Isopropyl Alcohol 70% v/v. Purpose: Antiseptic

USES:

Effective in destroying (harmful) bacteria to provide antiseptic cleansing recommended for repeated use .

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

On children less than 2 months of age

On open skin wounds

Stop use and ask a doctor if irritation or rash develops and lasts for more than 72 hours.

- Avoid contact with eyes
- If contact occurs
- Rinse thoroughly with water.

Do not store above 105F(41 C)

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

Water, Ricinus Communis Seed oil, Acrylates copolymer, Glycerin, Aloe Vera Juice, Isopropyl Myristate, Tocopheryl Acetate, Triethanolamine

Parfum

- 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.

Antiseptic , Hand Sanitizer



HAND SANITIZER ROYAL OUD

isopropyl alcohol 70% v/v gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:8 1451-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416 302) (ISOPROPYL ALCOHOL - UNII:ND2M416 302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CASTOR OIL (UNII: D5340Y2I9G)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81451-008-01	40 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/25/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/25/2021	

Labeler - Pame Eco Tech (204258441)

Registrant - Pame Eco Tech (204258441)

Establishment

Name	Address	ID/FEI	Business Operations
Pame Eco Tech		204258441	manufacture(81451-008)

Revised: 1/2021

Pame Eco Tech