

FAREWELL COLLECTION- antiseptic hand soap soap
Paveemol Company Limited

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.

Paveemol-Brisas Hand Soap Macadamia

Active Ingredient(s)

Benzalkonium chloride 0.1%

Purpose

Antiseptic

Use

To help reduce bacteria on hands.

Warnings

For external use only.

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

Apply on hands thoroughly, wash and rinse afterward.

Children under 6 years of age should be supervised when using this product.

Other information

- Store between 15 and 30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

acrylates copolymer, aloe barbadensis leaf extract, chlorphenesin, cocamidopropyl betaine, disodium EDTA, glycerin, maltodextrin, panthenol, PEG-40 hydrogenated castor oil, phenoxyethanol, PPG-26-Buteth-26, purified water USP, sodium benzoate, sodium hydroxide, sodium lauryl sulfate, tocopheryl acetate

Package Label - Principal Display Panel

Moisturizing Antiseptic Hand Soap

Our Antiseptic Liquid Hand Soap cleanses your hands of harmful germs and bacteria. Specially formulated with Benzalkonium Chloride to protect your skin and provide maximum care and moisture. This product gives you the confidence and protection you need for yourself and your family.

Say FAREWELL to all germs and bacteria!

Distributed by
Brisas del Caribe Corp
Carr 188 Km 0.7
San Isidro Ind Park
Canóvanas, PR 00729
happyetpr.com

  

Made in Thailand






Moisturizing Antiseptic Hand Soap

with Aloe Vera & Glycerin
Leaves Skin Soft & Clean
Alcohol-Free Antiseptic Lotion
MACADAMIA NUT

Net: 250 mL e 8.5 OZ

Drug Facts

Active Ingredient	Purpose
Benzalkonium chloride 0.1%	Antiseptic
Uses To help reduce bacteria on hands.	
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Questions or comments? Call 787-740-5317	

250 mL NDC:81892-117-11

FAREWELL COLLECTION			
antiseptic hand soap soap			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81892-117
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 mg in 100 mL	

Inactive Ingredients

Ingredient Name	Strength
CHLORPHENESIN (UNII: I670DAL4SZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PANTHENOL (UNII: WW9CM0O67Z)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
ACRYLATES CROSSPOLYMER-6 (UNII: 4GXD0Q3OS3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PPG-26-BUTETH-26 (UNII: 2II1K6TZ4P)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81892-117-11	250 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/23/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/20/2021	

Labeler - Pavemol Company Limited (660079138)

Establishment

Name	Address	ID/FEI	Business Operations
Pavemol Company Limited		660079138	manufacture(81892-117)