

FAREWELL COLLECTION- antiseptic hand cream cream
Brisas del Caribe Corp.

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.

Brisas-Paveemol Hand Cream

Active Ingredient(s)

Benzalkonium chloride 0.05 %.

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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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away 1 800-222-1222

Directions

- Apply on hands and leave until full absorption. No rinse is required.
- Supervise children under 6 years of age when using this product to avoid swallowing.

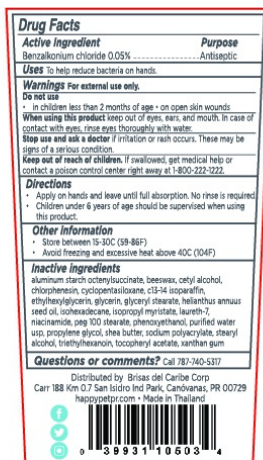
Other information

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

Inactive ingredients

aluminum starch octenylsuccinate, beeswax, cetyl alcohol, chlorphenesin, cyclopentasiloxane, C13-14 isoparaffin, ethylhexylglycerin, glycerin, glyceryl stearate, helianthus annuus seed oil, isohexadecane, isopropyl myristate, laureth-7, niacinamide, PEG 100 stearate, phenoxyethanol, purified water USP, propylene glycol, shea butter, sodium polyacrylate, stearyl alcohol, triethylhexanoin, tocopheryl acetate, xanthan gum

Package Label - Principal Display Panel



Our Antiseptic Hand Cream cleanses and protects from harmful germs. Specially formulated with Benzalkonium Chloride, Shea Butter and Glycerin to protect your skin and provide maximum care and moisture to relieve dry skin. This product gives you the confidence and protection you need for yourself and your family. Say FAREWELL to all germs and bacteria!

53 mL NDC : 12961-113-11

FAREWELL COLLECTION			
antiseptic hand cream cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12961-113
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)		BENZALKONIUM CHLORIDE	0.05 mg in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)			
LAURETH-7 (UNII: Z95S6G8201)			
CHLORPHENESIN (UNII: I670DAL4SZ)			

PHENOXYETHANOL (UNII: HIE492ZZ3T)
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)
NIACINAMIDE (UNII: 25X51I8RD4)
SUNFLOWER OIL (UNII: 3W1JG795YI)
GLYCERIN (UNII: PDC6A3C0OX)
WATER (UNII: 059QF0KO0R)
SHEA BUTTER (UNII: K49155WL9Y)
PEG-100 STEARATE (UNII: YD01N1999R)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
YELLOW WAX (UNII: 2ZA36H0S2V)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
CETYL ALCOHOL (UNII: 936JST6JCN)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
ISOHEXADECANE (UNII: 918X1OUF1E)
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
XANTHAN GUM (UNII: TTV12P4NEE)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12961-113-11	53 mL in 1 TUBE; Type 0: Not a Combination Product	06/21/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/21/2021	

Labeler - Brisas del Caribe Corp. (090399593)

Establishment

Name	Address	ID/FEI	Business Operations
Paveemol Company Limited		660079138	manufacture(12961-113)

Revised: 6/2021

Brisas del Caribe Corp.