

FAREWELL COLLECTION- antiseptic hand soap soap
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 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 the hands thoroughly, wash and rinse afterward.

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

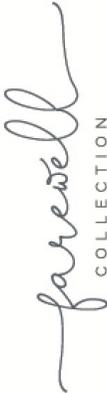
Other information

- Store between 15-30C (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

<p>Moisturizing Antiseptic Hand Soap</p> <p>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.</p> <p>Say FAREWELL to all germs and bacteria!</p> <p>Distributed by Brisas del Caribe Corp Carr 188 Km 0.7 San Isidro Ind Park Canóvanas, PR 00729 happypr.com</p> <p>  </p> <p>Made in Thailand</p> 	  <p>Moisturizing Antiseptic Hand Soap</p> <p>with Aloe Vera & Glycerin Leaves Skin Soft & Clean Alcohol-Free Antiseptic Lotion MACADAMIA NUT</p> <p>Net: 250 mL e 8.5 OZ</p>	<table border="1"> <tr> <th colspan="2">Drug Facts</th> </tr> <tr> <th>Active Ingredient</th> <th>Purpose</th> </tr> <tr> <td>Benzalkonium chloride 0.1%</td> <td>Antiseptic</td> </tr> <tr> <td colspan="2">Uses To help reduce bacteria on hands.</td> </tr> <tr> <td colspan="2">Warnings For external use only.</td> </tr> <tr> <td colspan="2">Do not use</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds </td> </tr> <tr> <td colspan="2">When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</td> </tr> <tr> <td colspan="2">Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</td> </tr> <tr> <td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away at 1-800-222-1222.</td> </tr> <tr> <td colspan="2">Directions</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • Apply on hands thoroughly, wash and rinse afterwards. • Children under 6 years of age should be supervised when using this product. </td> </tr> <tr> <td colspan="2">Other information</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) </td> </tr> <tr> <td colspan="2">Inactive ingredients</td> </tr> <tr> <td colspan="2">acrylates copolymer, aloe barbadensis leaf extract, chlorphenesin, cocamidopropyl betaine, disodium EDTA, fragrance, 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</td> </tr> <tr> <td colspan="2">Questions or comments? Call 787-740-5317</td> </tr> </table>	Drug Facts		Active Ingredient	Purpose	Benzalkonium chloride 0.1%	Antiseptic	Uses To help reduce bacteria on hands.		Warnings For external use only.		Do not use		<ul style="list-style-type: none"> • 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 at 1-800-222-1222.		Directions		<ul style="list-style-type: none"> • Apply on hands thoroughly, wash and rinse afterwards. • Children under 6 years of age should be supervised when using this product. 		Other information		<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 		Inactive ingredients		acrylates copolymer, aloe barbadensis leaf extract, chlorphenesin, cocamidopropyl betaine, disodium EDTA, fragrance, 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		Questions or comments? Call 787-740-5317	
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250 mL NDC:12961-117-11

FAREWELL COLLECTION

antiseptic hand soap soap

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12961-117
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: WW9CM0067Z)	
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: 059QF0KOOR)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
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:12961-117-11	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 - Brisas del Caribe Corp. (090399593)

Establishment

Name	Address	ID/FEI	Business Operations
Paveemol Company Limited		660079138	manufacture(12961-117)

Revised: 12/2022

Brisas del Caribe Corp.