

**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.*

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**Brisas-Paveemol Hand Soap Purple**

**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 in 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

**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  
happypr.com

Made in Thailand



**Moisturizing Antiseptic Hand Soap**

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

**SHADES OF PURPLE**

Net: 250 mL e 8.5 OZ

**Drug Facts**

Active Ingredient	Purpose
Benzalkonium chloride 0.1%	Antiseptic

**Uses**  
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- Avoid freezing and excessive heat above 40C (104F)

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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

250 mL NDC:12961-116-11

## FAREWELL COLLECTION

antiseptic hand soap soap

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:12961-116
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 mg in 100 mL

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12961-116-11	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(12961-116)

Revised: 12/2022

Brisas del Caribe Corp.