# 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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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 thoroughly, wash and rinse afterward.

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

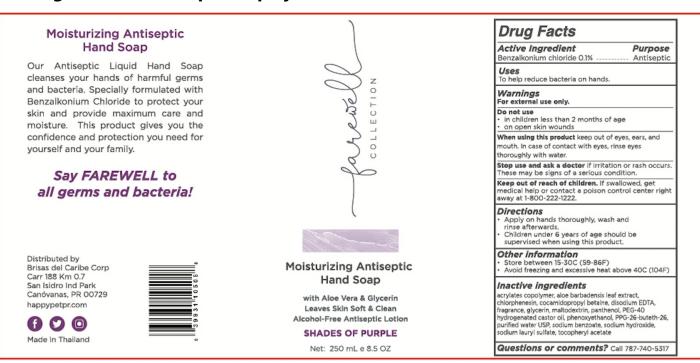
#### Other information

- 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



250 mL NDC:12961-116-11

# **FAREWELL COLLECTION**

antiseptic hand soap soap

antiseptic nand soap soap					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (S	Source)	NDC:	12961-116
Route of Administration	TOPICAL				
Active Ingradiant/Active	Maiaty				
Active Ingredient/Active Moiety					
Ingredient Name			<b>Basis of Stren</b>	igth	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)		BENZALKONIUM CHLORIDE		0.1 mg in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
CHLORPHENESIN (UNII: 1670DAL4SZ)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PANTHENOL (UNII: W/9CM0067Z)	
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: 50CF3011KX)	
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)	

l	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					
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
art333A	06/20/2021				
4	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date			

# Labeler - Brisas del Caribe Corp. (090399593)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Paveemol Company Limited		660079138	manufacture(12961-116)		

Revised: 12/2022 Brisas del Caribe Corp.