

PURITY BLEU ANTIBACTERIAL- benzalkonium chloride solution
Alben Internacional, S.A. de C.V.

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.

Active Ingredient(s)

Benzethonium Chloride 0.13% v/v. Purpose: Antibacterial

Purpose

Antibacterial, Hand Soap

Use

Uses - For handwashing to decrease bacteria on the skin

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

- Directions - pump into DRY hands - lather vigorously for at least 15 seconds - rinse and dry thoroughly
- 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

WATER, SODIUM LAURYL ETHER SULFATE, COCAMIDOPROPYL BETAINE, COCAMIDE DIETHANOLAMINE, GLYCERIN, ALOE BARBADENSIS EXTRACT, FRAGRANCE, BENZOPHENONE-4, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE,

Can Contain: RED No. 40 (CI 16035), RED No. 33 (CI 17200), BLUE No. 1 (CI 42090), YELLOW No. 5 (CI 19140), GREEN No. 3 (CI 42053), VIOLET 2 (CI 60730)

Package Label - Principal Display Panel

250 ml NDC:80955-010-01

ANTIBACTERIAL LIQUID HAND SOAP
Triclosan Free - With Aloe - Never tested on animals

purity[™]
BLEU

ANTIBACTERIAL LIQUID HAND SOAP
8.45 FL OZ (250ml)

DRUG FACTS

Active ingredient	Purpose
Benzalkonium Chloride 0.13%	Antibacterial

USE For handwashing to decrease bacteria on the skin.

WARNINGS: For external use only

When using this product: Avoid contact with eyes, in case of eye contact, flush with water.

Stop use and ask doctor if irritation or redness develops and if condition persists for over 72 hours.

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

DIRECTIONS: Pump into hands, wet as needed. Lather vigorously for at least 20 seconds, rinse and dry thoroughly.

INACTIVE INGREDIENTS
WATER, SODIUM LAURYL ETHER SULFATE, COCAMIDOPROPYL BETAINE, COCAMIDE DIETHANOLAMINE, GLYCERIN, ALGAE EXTRACT, FRAGRANCE, BENZOPHENONE-4, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE. Can Contain: RED No. 40 (CI 16035), RED No. 33 (CI 17200), BLUE No. 1 (CI 42090), YELLOW No. 5 (CI 19140), GREEN No. 3 (CI 42053), VIOLET 2 (CI 60730)

Batch and expiration date printed on the container

Don't expose to sun

Dispose of container in trash

MADE IN MEXICO, Alben Internacional S.A. de C.V. Av. De las Flores #10 Col. La Magdalena Atlixpac, Los Reyes La Paz Estado de Mexico ZC 56525

1000 ml NDC:80955-010-02

purityTM
BLEU

**ANTIBACTERIAL
LIQUID HAND SOAP REFILL**



34 FL OZ (1 Lt)

A new experience

DRUG FACTS

Active ingredient
Benzalkonium Chloride 0.13%.....

USE For handwashing to decrease

WARNINGS: For external use o

When using this product: Avoid contact, flush with water.

Stop use and ask doctor if irritat
persist for over 72 hours.

Keep out of reach of children. If
a Poison Control Center right awa

DIRECTIONS: Pump into hands,
least 20 seconds, rinse and dry th

INACTIVE INGREDIENTS

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FRAGRANCE, BENZOPHENONE-4
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(CI 17200), BLUE No. 1 (CI 42090),
(CI 42053), VIOLET 2 (CI 60730)

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MADE IN MEXICO, Alben Internacio
La Magdalena, Atlapaco, Los Rey



PURITY BLEU ANTIBACTERIAL

benzalkonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80955-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE (UNII: V5VD430 YW9)	
BENZOPHENONE-5 (UNII: 853Z42ZYAS)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	

GLYCERIN (UNII: PDC6A3C0OX)	
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
COCAMIDO PROPYL BETAINE (UNII: 5OCF3O11KX)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80955-010-01	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
2	NDC:80955-010-02	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Alben Internacional, S.A. de C.V. (813978616)

Registrant - Alben Internacional, S.A. de C.V. (813978616)

Establishment

Name	Address	ID/FEI	Business Operations
Alben Internacional, S.A. de C.V.		813978616	manufacture(80955-010)

Revised: 10/2020

Alben Internacional, S.A. de C.V.