ANTIBACTERIAL HAND- benzalkonium chloride liquid
CROSS BORDER MANUFACTURERS INC.

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.

ANTIBACTERIAL Hand Soap

DRUG FACTS

Active ingredient

Benzalkonium Chloride 0.13%

Purpose

Antimicrobial

Uses

For washing 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 a doctor if

- irritation and redness develop.

+ Keep out of reach of children.

- If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Wet hands with water, apply soap and rub for 20 seconds and rinse.

Inactive ingredients

Water, sodium laureth sulfate, cocamidopropyl betaine, sodium chloride, glycerin, polyquaternium –7, fragance, DMDM hydantoin, iodopropynyl butylcarbamate, butylene glycol, chamomilla recutita extract, aloe barbadensis extract, disodium EDTA, limonene, citric acid, blue 1 (CI 42090), yellow 5 (CI 19140), glycol distearate, cocamide MEA, Laureth-10

Questions?

Email: info@aglamee.com

Distributed by Cross-Border Manufacturers Inc.
Dover, DE, 19901

PRINCIPAL DISPLAY PANEL - 500 ML Bottle Label

aglameé

ANTIBACTERIAL
hand
soap

FRESH MINT
WITH CHAMOMILE +ALOE VERA

ANTIBACTERIAL
FORMULA

500 ML | 16.9 FL.OZ

ANTIBACTERIAL HAND

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78939-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
LAURETH-10 (UNII: BD7AST04GA)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:78939-002-01	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333A	09/16/2020	

Labeler - CROSS BORDER MANUFACTURERS INC. (117543128)

Establishment

Name	Address	ID/FEI	Business Operations
Absara Cosmetics SAPI de CV		816161236	MANUFACTURE(78939-002)