

AGROBAC FOAM WASH - benzalkonium chloride liquid
Deb USA, 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.

Drug Facts

Active ingredient

Benzalkonium Chloride, 1.30%

Purpose

Antibacterial

Uses

For hand washing to reduce 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.

Keep out of reach of children.

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

Directions

Apply to dry hands

Add water

Lather hands for 30 seconds

Rinse and dry hands thoroughly

Inactive ingredients

Water, Cocamidopropyl Betaine, Undeceth-7, Cocamidopropylamine Oxide, Cocamide DEA, Lauramine Oxide, Tetrasodium EDTA, Citric Acid, Magnesium Nitrate, Methylchloroisothiazolinone, Magnesium Chloride, Methylisothiazolinone.

deb

AgroBac Foam Wash

MADE IN USE

NSF

Nonfood Compounds Program Listed E-2 140060

1L

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11084-054
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.30 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
CO CO DIETHANOLAMIDE (UNII: 92005F972D)	
LAURAMINE OXIDE (UNII: 4F6FC4M18W)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MAGNESIUM NITRATE (UNII: 77CBG3UN78)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11084-054-20	2000 mL in 1 BOTTLE, PLASTIC		
2	NDC:11084-054-27	1000 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/01/2010	

Labeler - Deb USA, Inc. (607378015)

Establishment

Name	Address	ID/FEI	Business Operations
Deb USA, Inc.		607378015	manufacture