BYOTROL ANTIBACTERIAL FOAMING HAND SANITIZER - benzalkonium chloride liquid
Byotrol, 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 0.13%

Purpose

Antimicrobial

Uses

For hand sanitizing to decrease bacteria on the skin

Recommended for repeated use

Warnings

For external use only

When using this product avoid contact with eyes.

In case of eye contact, flush eyes with water.

Stop use and ask a doctor if irritation or redness develops, or if condition persists for more than 72 hours.

Keep out of reach of children.

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

Directions

Pump a small amount of foam onto hands

Rub thoroughly over all surfaces of both hands

Rub hands together briskly until dry

Inactive ingredients

Water, Cetrimonium Chloride, Laurtrimonium Chloride, Glycereth-17 Cocoate, Dihydroxyethyl Cocamine Oxide, Polyaminopropyl Biguanide, C8-10-Alkyl Polyglucoside, C12-15 Pareth-7, Citric Acid, Dimethicone

100%

Hygeine

Revolution

Byotrol

Alcohol Free

Kills Germs

Antibacterial Foaming

Hand Sanitizer

Powerful

No other FDA compliant hand antiseptic claims more.

Long Lasting

Foaming formula lasts, increasing wet contact time, to deliver the persistent performance Byotrol is known for.

Gentle

Alcohol Free Formula is hard on germs and soft on hands.

byotrol

Net Contents: 42.26 fl.Oz. (1,250ml)

100% Hygeine Revolution

BYOTROL®

ALCOHOL FREE
KILLS GERMS

ANTIBACTERIAL FOAMING HAND SANITIZER

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Product Code: BHS-1250

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Manufactured for: Byotrol, Inc. 100 Corporate Drive Suite J, Spartanburg, SC 29303 www.byotrol.com

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BYOTROL ANTIBACTERIAL FOAMING HAND SANITIZER

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:42719-346
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)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
LAURTRIMONIUM CHLORIDE (UNII: A81MSI0FIC)	
GLYCERETH-17 COCOATE (UNII: 3057VPT0KC)	
DIHYDROXYETHYL COCAMINE OXIDE (UNII: 8AR51R3BL5)	
POLIHEXANIDE (UNII: 322U039GMF)	
C12-15 PARETH-7 (UNII: 3XY03A79QH)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:42719-346-50	500 mL in 1 BOTTLE		
2	NDC:42719-346-51	210 mL in 1 BOTTLE		
3	NDC:42719-346-99	50 mL in 1 BOTTLE		
4	NDC:42719-346-06	1250 mL in 1 CARTRIDGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/08/2013	

Labeler - Byotrol, Inc. (084600340)

Establishment

Name	Address	ID/FEI	Business Operations
Bayscience Formulators Inc.		162930544	manufacture(42719-346)