STAY CLEAN FOAM HAND SANITIZER - hand sanitizer 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 Purpose

Benzalkonium Chloride 0.13%.....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 conditions 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, dihydroxypropyl PEG-5 linoleammonium chloride, glycereth-2 cocoate, behentrimonium chloride, dihydroxyethyl cocamine oxide, polyaminopropyl biguanide, dimethicone, C12-C15 pareth-7, alkyl polyglucoside

Stay Clean Foam Sanitizer

byotrol

Kills MRSA

Kills 99.9% of common germs that may cause illness, after a 15 second wet time

New and Improved Formula

Alcohol and Fragrance Free

Case Quantity 8

Not For Individual Resale

Moisturizing and conditioning formula

Net contents: 33.8 fl. oz. (1,000ml)



Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42719-345
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Benzalkonium Chloride (UNII: F5UM2KM3W7) (Benzalkonium - UNII:7N6JUD5X6Y)	Benzalkonium Chloride	0.13 mL in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
Dimethicone (UNII: 92RU3N3Y1O)	
Water (UNII: 059 QF0 KO0 R)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42719-345-50	500 mL in 1 BOTTLE		
2	NDC:42719-345-51	210 mL in 1 BOTTLE		
3	NDC:42719-345-83	1000 mL in 1 BAG		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333	09/18/2009		

Labeler - Byotrol, Inc. (084600340)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bayscience Formulators Inc.		162930544	manufacture	

Revised: 10/2009 Byotrol, Inc.