BYOTROL HAND SANITIZER - benzalkonium chloride liquid Advanced Hygienics LLC

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

Questions? 1-866-443-4509

byotrol

ANTIBACTERIAL FOAMING

HAND SANITIZER

ALCOHOL FREE KILLS GERMS

POWERFUL

LONG LASTING

GENTLE

Net Contents: 16.9 FL OZ (500mL)



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Polyglucoside, C12-18 Pareth-7, Dimethicone, Cetrimonium
Chloride, Laurtrimonium Chloride, Dihydroxyethyl Cocamine

Oxide, Glycereth-17 Cocoate, Citric Acid

Questions? 1-866-443-4509

BYOTROL HAND SANITIZER

benzalkonium chloride liquid

Item: BHS-51

LOT#

LAB-HS-17-01-110316

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63002-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM -BENZALKONIUM 1.3 mg UNII:7N6JUD5X6Y) CHLORIDE in $1\,\text{mL}$

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
CETRIMO NIUM CHLO RIDE (UNII: UC9 PE9 5 IBP)				
LAURTRIMO NIUM CHLO RIDE (UNII: A8 1MS 10 FIC)				
GLYCERETH-17 CO CO ATE (UNII: 3057VPT0KC)				
DIHYDRO XYETHYL CO CAMINE O XIDE (UNII: 8 AR51R3BL5)				
POLIHEXANIDE (UNII: 322U039GMF)				
CAPRYLYL GLUCO SIDE (UNII: V109 WUT6 RL)				
C12-15 PARETH-7 (UNII: 3XY03A79QH)				
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)				
DIMETHICO NE (UNII: 92RU3N3Y1O)				

	Packaging							
I	#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
		NDC:63002-002- 99	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/02/2014				
ı	2	NDC:63002-002-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2014				
	3	NDC:63002-002-12	1250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2014				

4 NDC:63002-002-75	9463 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 4/0 1/20 15			
Marketing Information					
Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not fin	al part333A	05/02/2014			

Labeler - Advanced Hygienics LLC (065359009)

Establishment						
Name	Address	ID/FEI	Business Operations			
Wisconsin Pharmacal Company		800873986	manufacture(63002-002)			

Revised: 12/2017 Advanced Hygienics LLC