FOAMING SANITIZING HAND- benzalkonium chloride soap OPI Correctional Industries

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.

Active Ingredient

Benzalkonium Chloride 0.13% w/w

Purpose

Antibacterial

Keep out of reach of children. If swallowed, contact a physician or poison control center.

 $\[Uses]$ For handwashing to decrease bacteria on skin

Directions Apply small amount, covering hands with product for 30 seconds. Add water, lather, rinse.

□Warnings

For external use only. Do not use in the eyes. If eye contact occurs, flush eyes with water.

Stop use and ask a doctor if redness and irritation occur and last for more than 72 hours.

Inactive Ingredients

water, cocamidopropyl PG-dimonium chloride phosphate, cocamidopropyl betaine, PEG-6 cocamide, laurtrimonium chloride, iodopropynyl butylcarbamate, methylisothiazolinone.



This container is coded for Recycling

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OPI CORRECTIONAL INDUSTRIES

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FOAMING SANITIZING HAND benzalkonium chloride soap Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:43196-683 Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.003 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)		
COCAMIDO PRO PYL PG-DIMO NIUM CHLO RIDE PHO SPHATE (UNII: H2KVQ74JM4)		
PEG-6 CO CAMIDE (UNII: YZ6NLA4O1E)		
LAURTRIMO NIUM CHLO RIDE (UNII: A8 1MS I0 FIC)		
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)		
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)		

ı	Packaging				
	# It	em Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC 09	:43196-683-	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	10/01/2015		

Labeler - OPI Correctional Industries (809174501)

Establishment				
Name	Address	ID/FEI	Business Operations	
Kutol Products Company		0 0 4 2 3 6 1 3 9	manufacture(43196-683)	

Revised: 1/2016 OPI Correctional Industries