4 SURE PLUS E3 INSTANT FOAM HAND SANITIZER - benzalkonium chloride liquid DevMar Products 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 0.1%

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

Wash hands with soap and water

Rinse with potable water

Pump a small amount of foam into palm of hand

Rub thoroughly over all surfaces of both hands

Rub hands together briskly until dry

Inactive ingredients

Water, cetrimonium chloride, laurtrimonium chloride, dihydroxyethyl cocamine oxide, glycereth-17 cocoate, citric acid

4 SURE Plus E3 Instant Foam Hand Sanitizer

Hand Sanitizer

Alcohol Free

Kills up to 99.9%

of germs on Hands

Refreshing and Soft on Skin

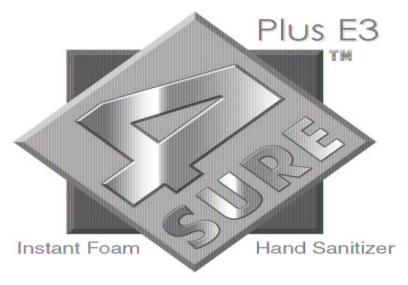
Acceptable for use in food processing facilities

NSF

Nonfood Compounds Program Listed E3

#147444

550 mL (18.6 fl. oz) Made in the U.S.A.



Hand Sanitizer
Alcohol Free
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of germs on Hands
• Refreshing & Soft on Skin

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Directions • Wash hands wi potable water • Pump a smal hand • Rub thoroughly over al hands together briskly until dry

Inactive ingredients Water, laurtrimonium chloride, dihydro glycereth-17 cocoate, citric ac



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4 SURE PLUS E3 INSTANT FOAM HAND SANITIZER

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54410-001
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	1 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
CETRIMO NIUM CHLO RIDE (UNII: UC9 PE95IBP)			
LAURTRIMO NIUM CHLO RIDE (UNII: A8 1MS I0 FIC)			
DIHYDRO XYETHYL CO CAMINE O XIDE (UNII: 8 AR51R3BL5)			
GLYCERETH-17 CO CO ATE (UNII: 3057VPT0KC)			
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:54410-001-01	50 mL in 1 BOTTLE, PLASTIC			
2	NDC:54410-001-02	210 mL in 1 BOTTLE, PLASTIC			
3	NDC:54410-001-03	550 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	0 1/10/20 13		

Labeler - DevMar Products LLC (809038255)

Establishment				
Name	Address	ID/FEI	Business Operations	
Maxpax LLC		027109390	manufacture(54410-001)	

Revised: 3/2013 DevMar Products LLC