HAND SANITIZER - benzalkonium chloride solution 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 the 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, Cetrimomium Chloride, Laurtrimonium Chloride, Dihydroxyethyl Cocamine Oxide, Glycereth-17 Cocoate, Citric Acid

Questions?

1-866-443-4509

American

Red Cross

Always Ready

Hand Sanitizer

Antibacterial Foaming

Alcohol-Free

Powerful and Long Lasting

Gentle

16.9 FL OZ (500 mL)

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Manufactured for Advanced Hygienics LLC, 6707 NE 117th Ave., Suite B-101, Vancouver, WA, USA 98662. ©2017 Advanced Hygienics LLC Contact us: info@advancedhygienics.com or Phone: 1-866-443-4509

LOT#/Exp.

Item: 100-250



LAB-HS-500-01 | C7137

HAND SANITIZER

benzalkonium chloride solution

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:63002-004

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 g in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
POLIHEXANIDE (UNII: 322U039GMF)			
CAPRYLYL GLUCO SIDE (UNII: V109 WUT6 RL)			
C12-15 PARETH-7 (UNII: 3XY03A79QH)			
DIMETHICO NE (UNII: 92RU3N3Y1O)			
CETRIMO NIUM CHLO RIDE (UNII: UC9 PE9 5 IBP)			
LAURTRIMO NIUM CHLO RIDE (UNII: A8 1MS 10 FIC)			
DIHYDRO XYETHYL CO CAMINE O XIDE (UNII: 8 AR51R3BL5)			
GLYCERETH-17 CO CO ATE (UNII: 3057VPT0 KC)			
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)			

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:63002-004- 33	9.76 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/18/2017	
2	NDC:63002-004- 99	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2017	
3	NDC:63002-004- 50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/18/2017	

Labeler - Advanced Hygienics LLC (065359009)

Establishment			
Name	Address	ID/FEI	Business Operations
Wisconsin Pharmacal Company		800873986	manufacture (63002-004)

Revised: 5/2017 Advanced Hygienics LLC