BAC OFF - benzalkonium chloride liquid Wayne Concept Manufacturing Co 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 ingredients Purpose

Benzalkonium Chloride 0.1%......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 into palms of hand.

Rub thoroughly over all surfaces of both hands.

Rub hands together briskly until dry.

Inactive ingredients:

Water (aqua), dihydroxypropyl PEG-5 linoleammonium chloride, glycereth-2-cocoate, behentrimonium chloride, dihydroxyethyl cocamine oxide.

Wayne

Select Line

BAC OFF

Instant Foam Hand Sanitizer

Manufactured by:

Wayne Concept Manufacturing Co., Inc.

Fort Wayne, IN 46825 260-482-8615

Net Contents: 1 U.S. Gallon (3.785 L)

Serving the maintenance community since 1933

BAC OFF

benzalkonium chloride liquid

Droduct	Information
Product	IIIIVI IIIduvii

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64495-2362
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

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l	Ingredient Name	Basis of Strength	Strength		
l	Benzalkonium Chloride (UNII: F5UM2KM3W7) (Benzalkonium - UNII:7N6JUD5X6Y)	Benzalkonium Chloride	0.1 mL in 100 mL		

Inactive Ingredients Ingredient Name Strength Water (UNII: 059QF0KO0R) Dihydroxypropyl Peg-5 Linoleammonium Chloride (UNII: 0Y0NQR2GH1) Glycereth-2 Cocoate (UNII: JWM00VS7HC) Behentrimonium Chloride (UNII: X7GNG3S47T) Dihydroxyethyl Cocamine Oxide (UNII: 8AR51R3BL5)

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64495-2362-8	532 mL in 1 BOTTLE, PUMP		
2	NDC:64495-2362-1	3785 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	03/31/2008	

Labeler - Wayne Concept Manufacturing Co Inc (198433179)

Establishment				
Name	Address	ID/FEI	Business Operations	
Wayne Concept Manufacturing Co Inc		198433179	manufacture	

Revised: 6/2010 Wayne Concept Manufacturing Co Inc