

CLEANPHIRST ALCOHOL FREE ANTISEPTIC HAND SANITIZER - benzalkonium chloride gel

Cleanphirst, 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.

Cleanphirst Alcohol Free Antiseptic Hand Sanitizer

Active Ingredient	Purpose
Benzalkonium Chloride 0.13 percent.....	Antiseptic

Uses

For hand washing to decrease bacteria on the skin.

Recommended for repeated use.

Warnings:

For external use only.

Do not use in the eyes.

Discontinue if irritation or redness develop.

If condition persists for more than 72 hours consult a doctor.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions: Wet hands thoroughly with product and allow to dry without wiping.

Inactive Ingredients: Behentrimonium Chloride, Citric Acid, Dihydroxyethyl Cocamine Oxide, Dihydroxypropyl PEG-5, Linoleammonium Chloride, Fragrance, Glycereth-2 Cocoate, Glycerin, Potassium Carbonate, Water.

Drug Facts	
Active Ingredient Benzalkonium Chloride 0.13%	Purpose Antiseptic
Uses: <ul style="list-style-type: none"> ■ For handwashing to decrease bacteria on the skin. ■ Recommended for repeated use. 	
Warnings: <ul style="list-style-type: none"> ■ For external use only. ■ Do not use in the eyes. ■ Discontinue if irritation or redness develop. If condition persists for more than 72 hours consult a doctor. ■ Keep out of reach of children. ■ If swallowed, get medical help or contact a Poison Control Center right away. 	
Directions: ■ Wet hands thoroughly with product and allow to dry without wiping.	
Inactive Ingredients: Behentrimonium Chloride, Citric Acid, Dihydroxyethyl Cocamine Oxide, Dihydroxypropyl PEG-5, Lindoleammonium Chloride, Fragrance, Glycereth-2 Cocoate, Glycerin, Potassium Carbonate, Water.	

Let No.:
 Exp. Date:
 Manufactured by: MicroPure Solutions, LLC
 1055 Stevenson Ct., Suite 105 W
 Roselle, IL 60172 United States

CLEANpHIRST

Alcohol Free

Antiseptic Hand Sanitizer

Kills up to 99.999 percent of germs

leaves skin soft

Won't Dry Out Hands

www.cleanphirst.com

125 Applications/1.7fl oz (50mL)

Manufactured by: MicroPure Solutions, LLC

1055 Stevenson Ct., Suite 15 W

Roselle, IL 60172

United States

Exp. Date:

Lot No.:



CLEANPHIRST ALCOHOL FREE ANTISEPTIC HAND SANITIZER

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52138-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BEHENTRIMONIUM CHLORIDE (UNII: X7GNG3S47T)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIHYDROXYETHYL COCAMINE OXIDE (UNII: 8AR51R3BL5)	
GLYCERETH-2 COCOATE (UNII: JWM00VS7HC)	
GLYCERIN (UNII: PDC6A3C0OX)	
POTASSIUM CARBONATE (UNII: BQN1B9B9HA)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52138-100-50	50 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333	05/12/2010	

Labeler - Cleanphirst, LLC (833241438)

Establishment			
Name	Address	ID/FEI	Business Operations
MicroPure Solutions, LLC		805764508	manufacture

Revised: 6/2010

Cleanphirst, LLC