

PREMIUM ANTIBACTERIAL HAND- benzalkonium chloride soap
Insolcorp, 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.

Premium Antibacterial Hand Soap

ACTIVE INGREDIENT

Benzalkonium Chloride 0.13%

PURPOSE

Antibacterial

USE

For washing to decrease bacteria on the skin

WARNINGS

For external use only

WHEN USING THIS PRODUCT AVOID CONTACT WITH EYES. In case of eye contact flush with water.

STOP USE AND ASK A DOCTOR IF irritation and redness develops

KEEP OUT OF THE REACH OF CHILDREN IF SWALLOWED, get medical help or contact a poison control center right away.

DIRECTIONS

Pump into dry hands and forearms, lather for at least 15 seconds, rinse and dry.

INACTIVE INGREDIENTS

Water, Caprylyl / Capryl Glucosides, Laurtrimonium Chloride, Cocamidopropylamine Oxide, Citric Acid, Fragrance

PRINCIPAL DISPLAY PANEL

PREMIUM ANTIBACTERIAL HAND SOAP

LEMON BLOSSOM

12 FL. OZ. (354 mL)



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According to the CDC, regular handwashing is one of the best ways to remove germs, avoid getting sick, and prevent the spread of germs to others. Whether you are at home, at work, traveling, or out in the community: handwashing with soap and water can protect you and your family.

DRUG FACTS	
ACTIVE INGREDIENT Benzalkonium Chloride 0.13%	PURPOSE Antibacterial
USE For washing to decrease bacteria on the skin	
WARNINGS For external use only	
WHEN USING THIS PRODUCT AVOID CONTACT WITH EYES. In case of eye contact flush with water. STOP USE AND ASK A DOCTOR IF irritation and redness develops. KEEP OUT OF THE REACH OF CHILDREN IF SWALLOWED, get medical help or contact a poison control center right away.	
DIRECTIONS Pump into dry hands and forearms, lather for atleast 15 seconds, rinse and dry.	
INACTIVE INGREDIENTS Water, Caprylyl / Capryl Glucosides, Laurtrimonium Chloride, Cocamidopropylamine Oxide, Citric Acid, Fragrance	



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PREMIUM ANTIBACTERIAL HAND

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:748 11-002
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 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
LAURTRIMONIUM CHLORIDE (UNII: A81MSI0FIC)	
COCAMIDOPROPYLAMINE OXIDE (UNII: M4SL82J7HK)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:748 11-002-02	354 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/08/2020	

Labeler - Insolcorp, LLC (080539371)

Establishment

Name	Address	ID/FEI	Business Operations
Insolcorp, LLC		080539371	manufacture(748 11-002)

Revised: 12/2020

Insolcorp, LLC