

**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.*

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**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

8 FL. OZ. (240 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.

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



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## PREMIUM ANTIBACTERIAL HAND

benzalkonium chloride soap

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:748 11-002
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6 Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DECYL GLUCOSIDE</b> (UNII: Z17H97EA6 Y)	
<b>LAURTRIMONIUM CHLORIDE</b> (UNII: A81MSI0FIC)	
<b>CO CAMIDO PROPYLAMINE OXIDE</b> (UNII: M4SL82J7HK)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:748 11-002-01	240 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/10/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333A	12/10/2020	

**Labeler** - Insolcorp, LLC (080539371)

**Establishment**

Name	Address	ID/FEI	Business Operations
Insolcorp, LLC		080539371	manufacture(74811-002)

Revised: 12/2020

Insolcorp, LLC