

ANTI-BACTERIAL HAND- benzalkonium chloride soap

Collective Science Integration

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.

ACTIVE INGREDIENTS

BENZALKONIUM CHLORIDE 0.25%

DIRECTIONS

LATHER VIGOROUSLY AND WASH SKIN. RINSE AND DRY THOROUGHLY.

PURPOSE

ANTIBACTERIAL

USES

FOR HAND WASHING TO DECREASE BACTERIA ON THE SKIN.

INACTIVE INGREDIENTS

WATER

KEEP OUT OF REACH OF CHILDREN.

WARNINGS

FOR EXTERNAL USE ONLY

Drug Facts**Active ingredients**

Benzalkonium Chloride 0.25%

Purpose

Antibacterial

Uses • for hand 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 reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.**Directions**

Lather vigorously and wash skin. Rinse and dry thoroughly.

Inactive ingredients Water, TEA-Lauryl Sulfate, Cocamidopropyl Hydroxylamine, Glycerin, Sodium Chloride, Lavender, Peg-150 Distearate, Glycol Stearate, Cocamide DIPA, Disodium EDTA, Methyl Chloro Isothiazolinone, Methyl Isothiazolinone, Citric Acid.

Dist. by P&P International Inc.

El Monte, CA 91731

Made in USA

www.csihealth.org

**ANTI-BACTERIAL
HAND SOAP****KILLS 99% OF GERMS**Lavender + Rosemary
Essential Oils

8 FL. OZ.

**ANTI-BACTERIAL HAND**

benzalkonium chloride soap

Product Information**Product Type**

HUMAN OTC DRUG

Item Code (Source)

NDC:90055-209

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.25 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CO CAMIDO PRO PYL HYDRO XYSUL TAIN E (UNII: 62V75NI93W)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
TRIETHANOLAMINE LAURYL SULFATE (UNII: E8458C1KAA)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
WATER (UNII: 059QF0KO0R)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
DISODIUM ETHYLENE DICO CAMIDE PEG-15 DISULFATE (UNII: QI9A6U005W)	

CITRIC ACID ACETATE (UNII: DSO12WL7AU)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:90055-209-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/09/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	10/09/2020	

Labeler - Collective Science Integration (133591508)

Establishment			
Name	Address	ID/FEI	Business Operations
P&P International		133591508	manufacture(90055-209)