PROTEX BALANCE ANTIBACTERIAL HAND- benzalkonium chloride liquid Colgate-Palmolive Company

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.

Protex_®

Drug Facts

Active ingredient

Benzalkonium chloride 0.13%

Purpose

Antibacterial

Use

helps eliminate bacteria on hands

Warnings

For external use only

When using this product, avoid contact with eyes. In case of eye contact, flush with water.

Keep out of reach of children, except under adult supervision. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply to hands, wash and rinse. Unique Formula. Refill only with Protex

Inactive ingredients

Water, Cetrimonium Chloride, Glycerin, Lauramidopropylamine Oxide, Cocamide MEA, Citric Acid, Sodium Benzoate, PEG-120 Methyl Glucose Dioleate, Fragrance, Sodium Chloride, Tetrasodium EDTA, Yellow 5, Red 33.

Questions?

1-800-443-0602

Distributed by:

COLGATE-PALMOLIVE COMPANY, Distr. Guaynabo, P.R. 00968-1705

PRINCIPAL DISPLAY PANEL - 221 mL Bottle Label

Eliminates 99.9% of Bacteria*

Protex_®

For the Good Health of your Skin Daily Protection Against Bacteria

BALANCE

DERMATOLOGIST TESTED

Antibacterial Liquid Hand Soap

9904820 7.5 FL OZ (221 mL)

Eliminates 99.9% of Bacteria*

For the Good Health of your Skin Daily Protection Against Bacteria

BALANCE

Antibacterial Liquid Hand Soap

7.5 FL OZ (221 mL)

- ✓ Antibacterial Protection
- ✓ Everyday All Family Use BALL ✓ Eliminates 99.9% of Bacteria®

Antibacterial **Liquid Hand Soap**

Protex® Balance liquid hand soap has antibacterial protection and is clinically proven to eliminate 99.9% of bacteria®. An excellent everyday choice for the entire family. Protex® soaps give you and your family the antibacterial protection you need.

Drug Facts

Active ingredient Purpose

Benzalkonium chloride 0.13%.....Antibacterial

se helps eliminate bacteria on hands

Drug Facts (continued)

Directions Apply to hands, wash and rinse. Unique Formula. Refill only with Protex

Inactive ingredients Water, Cetrimonium

Warnings For external use only

When using this product, avoid contact with eyes. In case of eye contact, flush with water.

Keep out of reach of children, except under adult supervision. If swallowed, get medical help or contact a Poison Control Center right away.

*Eliminates 99.9% of E. coli bacteria

Oxide, Cocamide MEA, Citric Acid, Sodium Benzoate, PEG-120 Methyl Glucose Dioleate, Fragrance, Sodium Chloride, Tetrasodium EDTA, Yellow 5, Red 33.

Questions? 1-800-443-0602

Distributed by:

COLGATE-PALMOLIVE COMPANY, Distr.
Guaynabo, P.R. 00968-1705







PROTEX BALANCE ANTIBACTERIAL HAND

benzalkonium chloride liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:35000-255

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Inactive Ingredients Ingredient Name WATER (UNII: 059QF0KO0R) CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP) GLYCERIN (UNII: PDC6A3C0OX) LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV) COCO MONOETHANOLAMIDE (UNII: C80684146D) ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) SODIUM BENZOATE (UNII: OJ245FE5EU) PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V) SODIUM CHLORIDE (UNII: 451W47IQ8X) EDETATE SODIUM (UNII: MP1J8420LU) FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)

Product Characteristics			
Color	ORANGE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
# Itei	Item Code Package Description		Marketing Start Date	Marketing End Date
1 NDC:3	35000-255-	221 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/17/2022	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part333E	10/17/2022		
FINAL				

Labeler - Colgate-Palmolive Company (001344381)

Establishment			
Name	Address	ID/FEI	Business Operations
Colgate-Palmolive Company		079342773	ANALYSIS(35000-255), MANUFACTURE(35000-255), PACK(35000-255), LABEL(35000-255)

Establishment				
Name	Address	ID/FEI	Business Operations	
VeePak, Inc		874763303	MANUFACTURE(35000-255)	

Revised: 12/2019 Colgate-Palmolive Company