

FOAMING ANTIBACTERIAL HAND WASH- 0.13% benzalkonium chloride soap

RJ Schinner

RJ Schninner F213F

Dosage and Administration

Directions Apply small amount, covering hands with product for 30 seconds. Add water, lather, rinse.

Inactive Ingredients

Inactive Ingredients Water, Cocamidopropyl Betaine, Cocamidopropyl PG-Dimonium Chloride Phosphate, PEG-6 Cocamide, Laurtrimonium Chloride, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Fragrance, Iodopropynyl Butylcarbamate, Methylisothiazolinone, Yellow 5, Red 33.

Indications and Uses

Uses For handwashing to decrease bacteria on the skin.

Keep Out Of Reach Of Children

Keep out of reach of children. If swallowed, contact a physician or poison control center.

Purpose Section

Purpose Antibacterial Agent

Active Ingredient Section

Active Ingredient Benzalkonium Chloride 0.13% w/w

Warnings Section

Warnings

For external use only

Avoid contact with eyes. If contact occurs, flush with water.

Stop use and ask a doctor if, in rare instances, redness or irritation develops and persists for more than 72 hours

Primary Display Label

#PP7802F



FOAMING ADVANCED ANTIBACTERIAL HAND SOAP

with Aloe and Vitamin E

JABÓN ESPUMOSO ANTIBACTERIAL PARA MANOS. FÓRMULA AVANZADA
con Aloe y Vitamina E**Drug Facts****Active Ingredient**

Benzalkonium Chloride 0.13% w/wAntibacterial Agent

Purpose**Uses** For handwashing to decrease bacteria on skin.**Warnings**

For external use only.

Avoid contact with eyes. If contact occurs, flush with water.**Stop use and ask a doctor if,** in rare instances, redness or irritation develop and persists for more than 72 hours.**Keep out of reach of children.** If swallowed, contact a physician or poison control center.**Directions** Apply small amount, covering hands with product for 30 seconds. Add water, lather, rinse.**Inactive Ingredients** Water, Cocamidopropyl Betaine, Cocamidopropyl PG-Dimonium Chloride Phosphate, PEG-6 Cocamide, Laurtrimonium Chloride, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate (Vitamin E), Fragrance, Iodopropynyl Butylcarbamate, Methylisothiazolinone, Yellow 5, Red 33.

Ingrediente Activo Cloruro de benzalconio 0.13 % en peso (Agentes antibacteriano) **Usos** Se usa para el lavado de manos a fin de disminuir las bacterias en la piel. **Advertencias** Solamente para uso externo. No lo utilice en los ojos. En casos raros de irritación y enrojecimiento, suspenda el uso. Si el estado persiste durante más de 72 horas consulte con un médico. Si se ingiere llame a un médico o a un centro de control de venenos. Mantenga fuera del alcance de niños. **Modo de Empleo** Aplique una cantidad pequeña de producto sobre las manos, cubriendo las manos durante 30 segundos. Añada agua, forme espuma y enjuague. **Ingredientes Inactivos** Agua, Cocamidopropil betaina, Cloruro y Fosfato de Cocamidopropil PG- dimonio, PEG - 6 Cocamida, Cloruro de Laurtrimonio, Jugo de Hoja de Aloe Barbadensis, Acetato de tocoferol (Vitamina E), Fragancia, Yodopropinil Butilcarbamat, Metilisotiazolinona, Amarillo 5, Rojo 33.

Net Contents: 1000 mL (33.8 Fl. Oz.)**Manufactured in the USA**
in a LEED® Silver certified facility

DISTRIBUTED BY:

RJ SchinnerRJ SCHINNER CO. INC
N89 W14700 Patrita Dr.
Menomonee Falls, WI 53051
(262) 797- 7180www.performanceplus-products.com**FOAMING ANTIBACTERIAL HAND WASH**

0.13% benzalkonium chloride soap

Product Information**Product Type**

HUMAN OTC DRUG

Item Code (Source)

NDC:71303-213

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.013 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
WATER (UNII: 059QF0KO0R)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
LAURTRIMONIUM CHLORIDE (UNII: A81MSI0FIC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4)	
PEG-6 COCAMIDE (UNII: YZ6NLA4O1E)	
HC YELLOW NO. 5 (UNII: I844A312T7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71303-213-31	1000 mL in 1 BAG; Type 0: Not a Combination Product	03/30/2017	
2	NDC:71303-213-41	1000 mL in 1 BAG; Type 0: Not a Combination Product	03/30/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	03/30/2017	

Labeler - RJ Schinner (023432909)

Registrant - Kutol Products, Inc. (004236139)

Establishment

Name	Address	ID/FEI	Business Operations
Kutol Products, Inc.		004236139	manufacture(71303-213)