

FOAMING ANTIBACTERIAL HAND WASH- 0.13% benzalkonium chloride soap RJ Schinner

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.

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, Cocamidopopyl Betaine, Cocamidoprpyl 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	Purpose
Benzalkonium Chloride 0.13% w/w	Antibacterial Agent

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 Butilcarbamato, 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 Schinner

RJ SCHINNER CO. INC
N89 W14700 Patrita Dr.
Menomonee Falls, WI 53051
(262) 797- 7180

www.performanceplus-products.com

LA117W

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 not final	part333E	03/30/2017	

Labeler - RJ Schinner (023432909)

Registrant - KutoI Products, Inc. (004236139)

Establishment

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

Revised: 8/2023

RJ Schinner