

FOAMING SANITIZER- benzalkonium chloride 0.13% liquid

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 Schinner F683

Dosage and Administration

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

Inactive Ingredient Section

Inactive Ingredients Water, Cocamidopropyl Betaine, Laurtrimonium Chloride, Cocamidopropyl PG-Dimonium Chloride Phosphate, Peg-6 Cocamide, Iodopropynyl Butylcarbamate, Methylisothiazolinone

Indications and Usage Section

Uses For handwashing to help reduce bacteria on the skin that could cause disease.

Keep Out of Reach of Children

Keep Out Of Reach Of Children If swallowed, contact a physician or poison control center.

OTC Purpose Section

Purpose Antibacterial Agent

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.


OTC - Active Ingredient Section

Active Ingredient Benzalkonium Chloride 0.13% w/w

Package Label Display

PP7804F 1085F

#PP7804F



FOAMING E2 SANITIZING HAND SOAP
with moisturizers

JABÓN ESPUMOSO DESINFECTANTE E2 PARA MANOS
con hidratantes

Drug Facts

Active Ingredient	Purpose
Benzalkonium Chloride 0.13% w/w.....	Antibacterial Agent

Uses For handwashing to help reduce bacteria on the skin that could cause disease.

Warnings

For external use only.

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

Stop use if, in rare instances, redness or irritation develop. If condition persists for more than 72 hours, consult a physician.

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 PG-Dimonium Chloride Phosphate, Cocamidopropyl Betaine, PEG-6 Cocamide, Laurtrimonium Chloride, Iodopropynyl Butylcarbamate, Methylisothiazolinone.

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, suspenda el uso si se causa irritación y enrojecimiento. 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. **Mode 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, Cloruro y Fosfato de Cocamidopropil PG- dimonio, Cocamidopropil Betaine, PEG - 6 Cocamida, Cloruro de Laurtrimonio, Yodopropinil Butilcarbamato, Metilisotiazolinona.

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
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www.performanceplus-products.com

LA117

FOAMING SANITIZER			
benzalkonium chloride 0.13% liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71303-683
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)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4)	
LAURTRIMONIUM CHLORIDE (UNII: A81MSI0FIC)	
PEG-6 COCAMIDE (UNII: YZ6NLA4O1E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71303-683-41	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(71303-683)

Revised: 8/2023

RJ Schinner