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.

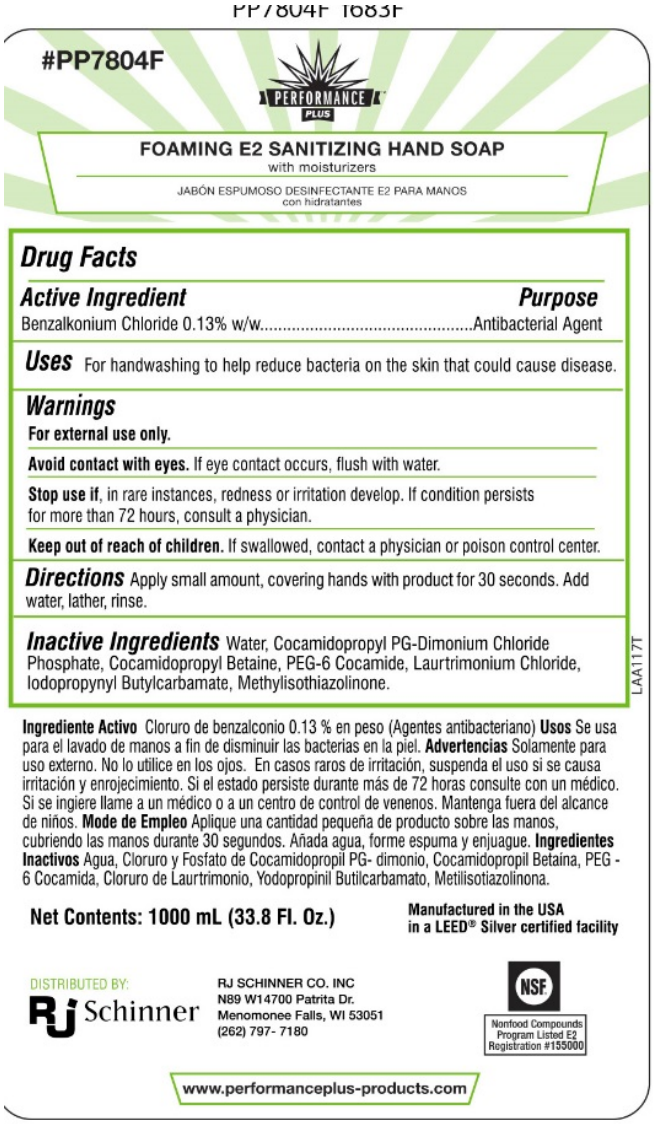
Avoid contact with eyes. If contact ocurrs, flush with water

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



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 - Kutol Products, Inc. (004236139)

Establishment

Name	Address	ID/FEI	Business Operations
Kutol Products, Inc		004236139	manufacture(71303-683)

Revised: 8/2023 RJ Schinner