FOAMING INSTANT HAND SANITIZER- 0.13% benzakonium chloride 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 F207

Dosage and Administration Section

Directions: Apply a small amount to palm. Briskly rub, covering hands with product until dry.

Inactive Ingredient Section

Inactive Ingredients: Water, Propylene Glycol, Cocamidopropyl Betaine, Aloe Barbadensis Leaf Juice, Tocopheral Acetate, Peg-& Glyceral Cocoate, Fragrance, Phenoxyethanol, Tetrasodium EDTA

Indications and Usage Section

Hand Sanitizer to help reduce bacteria on the skin that could cause disease. Intended for repeated use.

Keep Out Of Reach Of Children Section

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

OTC Purpose Section

Purpose: Antibacterial Agent

OTC Active Ingredient Section

Active Ingredient: Benzalkonium Chloride 0.13% w/w

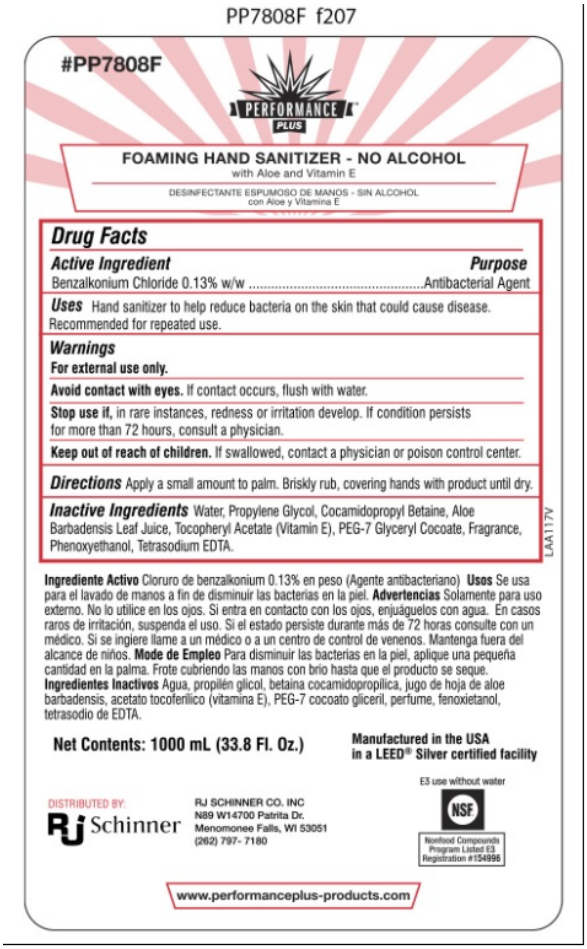
Warnings Section

Warnings: For External Use Only

Contact with Eyes: If contact occurs, flush with water

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

Primary Display Label



FOAMING INSTANT HAND SANITIZER

0.13% benzakonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71303-207
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**
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYLENE GLYCOL 1,2-DISTEARATE (UNII: T65PN3O37H)	
EDETATE SODIUM (UNII: MP1J8420LU)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71303-207-41	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2017	
2	NDC:71303-207-31	1000 mL in 1 BOTTLE; 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(71303-207)

Revised: 8/2023 RJ Schinner