FOAMING HAND SANITIZER WITH ALOE- benzalkonium chloride liquid APOLLO HEALTH AND BEAUTY CARE

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.

DRUG FACTS BOX (BACK LABEL)

ACTIVE INGREDIENT

BENZALKONIUM CHLORIDE 0.1% (ANTISEPTIC)

USES AND DIRECTIONS

- **USES:** TO HELP REDUCE BACTERIA ON THE SKIN THAT COULD CAUSE DISEASE. RECOMMENDED FOR REPEATED USE.
- **DIRECTIONS:** PUMP DESIRED AMOUNT ONTO HANDS AND RUB UNTIL YOUR SKIN IS DRY. CHILDREN UNDER 6 YEARS OF AGE SHOULD BE SUPERVISED WHEN USING THIS PRODUCT.

WARNINGS

• FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT

• AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE WITH WATER. AVOID CONTACT WITH BROKEN SKIN.

STOP USE AND ASK A DOCTOR IF

• SKIN IRRITATION OR REDNESS DEVELOPS AND LASTS.

KEEP OUT OF REACH OF CHILDREN

 IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

PACKAGE FRONT AND BACK LABELS

• 8OZ FRONT AND BACK LABELS: nc08.jpg



Drug Facts Active Ingredient **Purpose** Benzalkonium Chloride 0.1% Antiseptic Uses* To help reduce bacteria on the skin that could cause disease. Recommended for repeated use. Warnings For external use only. When using this product * avoid contact with eyes. If contact occurs, rinse with water. Avoid contact with broken skin. Stop using this product and ask doctor if * irritation or rash develops and lasts Keep out of reach of children In case of accidental ingestion, get medical help or contact a Poison Control Center immediately. Directions Pump desired amount onto hands and rub until your skin is dry.

 Children under 6 years of age should be supervised when using this product

Inactive Ingredients: Water (Aqua), Aloe Barbadensis Leaf Juice, Camellia Sinensis Leaf Extract, Fragrance (Parfum), DMDM Hydantoin, Sodium Hydroxide, Blue 1, Yellow 5.



FOAMING HAND SANITIZER WITH ALOE

benzalkonium chloride liquid

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:63148-240 Route of Administration TOPICAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1000 mL in 100 mL			

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:63148-240-08	236 mL in 1 BOTTLE, PUMP				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333	06/25/2010			

Labeler - APOLLO HEALTH AND BEAUTY CARE (201901209)

Revised: 6/2010 APOLLO HEALTH AND BEAUTY CARE