### FOAMING HAND SANITIZER - benzalkonium chloride gel TOPCO ASSOCIATES LLC

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.

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### **DRUG FACTS**

### **ACTIVE INGREDIENT**

BENZALKONIUM CHLORIDE 0.1 PERCENT

### **PURPOSE**

**ANTIMICROBIAL** 

### **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.

### STOP USING THIS PRODUCT AND ASK DOCTOR IF

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.

### **DIRECTIONS**

PUMP ENOUGH PRODUCT TO YOUR PALM TO THOROUGHLY COVER YOUR HANDS, RUB TOGETHER UNTIL DRY.

### **QUESTION OR COMMENTS**

1-888-423-0139

### **INACTIVE INGREDIENTS**

WATER, POLYSORBATE 20, ETHYLHEXYL METHOXYCINNAMATE, BUTYL METHOXYDIBENZOYLMETHANE, ETHYLHEXYL SALICYLATE, PPG-26-BUTETH-26, PEG-40 HYDROGENATED CASTOR OIL, ALOE BARBADENSIS LEAF JUICE, FRAGRANCE, TETRASODIUM EDTA, DMDM HYDANTOIN, SODIUM HYDROXIDE, BLUE 1 (CI 42090), YELLOW 5 (CI 19140).

# TopCare.

## **FOAMING** hand sanitizer

non-alcohol formula kills 99.99% of germs with moisturizers

WITH ALOE

8 FL OZ (236 mL)

### **Drug Facts**

Active ingredient Benzalkonium Chloride 0.1% ...

Uses ■To help reduce bacteria on the skin that could cause disease. Recommended for

### Warnings

#### For external use only.

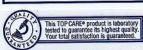
When using this product a avoid contact with eyes. If contact occurs, rinse with water Stop using this product and ask doctor if ■ irritation or redness develops and lasts.

Keep out of reach of children ■In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions ■ Pump enough product to your palm to thoroughly cover your hands, rub

#### together until dry. Questions/Comments? 1-888-423-0139

Inactive ingredients: Water (Aqüa), Polysorbate 20, Ethylhexyl Methoxycinnamate, Butyl Methoxydibenzoylmethane, Ethylhexyl Salicylate, PPG-26-Buteth-26, PEG-40 Hydrogenated Castor Oil, Aloe Barbadensis Leaf Juice, Fragrance (Parfum), Tetrasodium EDTA, DMDM Hydantoin, Sodium Hydroxide, Blue 1 (Cl 42090), Yellow 5 (Cl 19140).



DISTRIBUTED BY TOPCO ASSOCIATES LLC 7711 GROSS POINT ROAD, SKOKIE, IL 60077 ©TOPCO AHB 1210 QUESTIONS? 1-888-423-0139 topcare@topco.com

MADE IN CANADA



### FOAMING HAND SANITIZER

benzalkonium chloride gel

### **Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:36800-240

Route of Administration

TOPICAL

Ingredient Name

### **Active Ingredient/Active Moiety**

**DMDM HYDANTO IN (UNII: BYR0546 TOW)** SODIUM HYDRO XIDE (UNII: 55X04QC32I) FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

8			
E (UNII:	F5UM2KM3W7	7) (BENZALKONIU	M -

Ingredient Name

**Basis of Strength** 

Strength

BENZALKO NIUM CHLO RIDE UNII:7N6JUD5X6Y)

BENZALKONIUM **CHLORIDE** 

 $0.1\,\mathrm{mL}$ in 100 mL

Strength

### **Inactive Ingredients**

8
WATER (UNII: 059QF0KO0R)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
O CTINO XATE (UNII: 4Y5P7MUD51)
AVOBENZONE (UNII: G63QQF2NOX)
OCTISALATE (UNII: 4X49 Y0 59 6 W)
CASTOR OIL (UNII: D5340 Y2I9 G)
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)
.ALPHATO COPHEROL ACETATE, D- (UNII: A7E6112E4N)
EDETATE SO DIUM (UNII: MP1J8420 LU)

### FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:36800-240-08	236 mL in 1 BOTTLE			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333E	06/23/2011			

### Labeler - TOPCO ASSOCIATES LLC (006935977)

### Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture		

Revised: 6/2011 TOPCO ASSOCIATES LLC