# ANTIMICROBIAL FOAMING FALLING RAIN- benzethonium 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.

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#### **DRUG FACTS**

#### ACTIVE INGREDIENT

BENZETHONIUM CHLORIDE 0.1 PERCENT

#### **PURPOSE**

ANTIMICROBIAL

#### **USES**

FOR WASHING TO DECREASE BACTERIA ON THE SKIN.

#### **WARNINGS**

FOR EXTERNAL USE ONLY.

#### KEEP OUT OF REACH OF CHILDREN

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

#### WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE WITH WATER.

#### STOP USING THIS PRODUCT AND ASK A DOCTOR

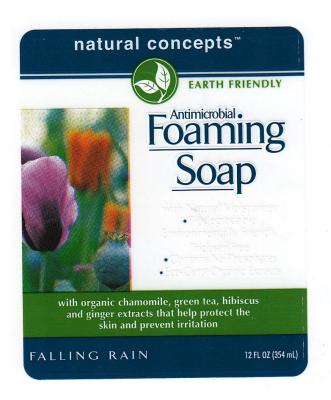
IF IRRITATION OR REDNESS DEVELOPS AND LASTS.

#### **DIRECTIONS**

PUMP INTO WET HANDS. WORK INTO A LATHER VIGOROUSLY. RINSE THOROUGHLY.

#### INACTIVE INGREDIENTS

WATER, COCAMIDOPROPYL BETAINE, GLYCERIN, DECYL GLUCOSIDE, POLYQUATERNIUM-7, FRAGRANCE, CAMELLIA SINENSIS, ZINGIBER OFFICINALE, HIBISCUS SABDARIFFA, CHAMOMILA RECUTITA, CITRIC ACID, ORIGANUM VULGARE LEAF EXTRACT, THYMUS VULGARE (THYME) EXTRACT, CINNAMOMUM ZEYLANICUM BARK EXTRACT, ROSEMARINUS OFFICINALIS (ROSEMARY) LEAF EXTRACT, LAVANDULA ANGUSTIFOLIA (LAVENDER) FLOWER EXTRACT, HYDRASTIS CANADENSIS (GOLDEN SEAL) ROOT EXTRACT, TETRASODIUM EDTA, GREEN 5, RED 33, YELLOW 5.



#### **Drug Facts**

Active Ingredient

**Purpose** 

Benzethonium Chloride 0.1 % ------ Antimicrobial

Use \* For washing to decrease bacteria on the skin.

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 a 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 into wet hands ■ work into a lather vigorously ■ rinse thoroughly

Other information store at room temperature

Inactive Ingredients: Water, Cocamidopropyl Betaine, Glycerin, Decyl Glucoside, Polyquaternium-7, Fragrance, Camellia Sinensis\*, Zingiber Officinale\*, Hibiscus Sabdariffa\*, Chamomilla Recutita\*, Citric Acid, Origanum Vulgare Leaf Extract, Thymus Vulgaris (Thyme) Extract, Cinnamomum Zeylanicium Bark Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Lavandula Angustifolia (Lavender) Flower Extract, Hydrastis Canadensis (Golden Seal) Root Extract, Tetrasodium EDTA, D&C Green 5, D&C Red 33, FD&C Yellow 5. \*Ecocert extracts

Manufactured by: Apollo Health and Beauty Care Concord, Ont. Product of Canada

exceeds current and future Biological Oxygen Demand requirements



#### ANTIMICROBIAL FOAMING FALLING RAIN

benzethonium chloride liquid

#### **Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63148-241

Route of Administration

TOPICAL

#### Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength	
	BENZETHONIUM CHLORIDE	0.1 mL in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
DECYL GLUCO SIDE (UNII: Z17H97EA6Y)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GINGER (UNII: C5529G5JPQ)	
HIBISCUS SABDARIFFA FLOWER (UNII: 45TGG6 IU6M)	
CHAMO MILE (UNII: FGL3685T2X)	
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)	

OREGANO (UNII: 0E5AT8T16U)	
THYME (UNII: CW657OBU4N)	
CINNAMON BARK OIL (UNII: XE54U569EC)	
ROSEMARY (UNII: IJ67X351P9)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19 AH1RAF4M)	
GOLDENSEAL (UNII: ZW3Z11D0JV)	
EDETATE SO DIUM (UNII: MP1J8420 LU)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63148-241-12	354 mL in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	07/22/2011		

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

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

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

Revised: 7/2011 APOLLO HEALTH AND BEAUTY CARE