FRUIT OF THE EARTH MEYER LEMON SCENTED ANTIBACTERIAL HAND WITH CANADIAN WILLOWHERB- benzethonium chloride soap FRUIT OF THE EARTH, INC.

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.

Fruit of the Earth Meyer Lemon Scented Antibacterial Hand Soap with Canadian Willowherb

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Use

helps reduce bacteria on hands

Warnings

For external use only

Do not use

on infants under 6 months of age

When using this product

avoid contact with eyes. In case of contact, flush with water.

Stop use and ask a doctor if

irritation occurs.

Keep out of reach of chlidren

except under adult supervision. If swallowed, get medical help or contract a Poison Control right away.

Directions

Inactive ingredients

Water, Decyl Glucoside, Glycerin, Cocamidopropyl Betaine, PEG-120 Methyl Glucose Dioleate, Fragrance, Phenoxyethanol, Citric Acid, Epilobium Angustifolium Flower/Leaf/Stem Extract, Tetrasodium EDTA, Alcohol.



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benzethonium chloride soap

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Product Information								
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:62217-085				
Route of Administration	TOPICAL							
Active Ingredient/Active Moiety								
Ingredient Name			Basis of Stre	ength	Strength			
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)		BENZALKONIUM CHLORIDE		1.3 mg in 1 mL				
Inactive Ingredients								
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Strength

Ingredient Name

PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)

GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
EDETATE SODIUM (UNII: MP1J8420LU)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
EPILOBIUM ANGUSTIFOLIUM FLOWERING TOP (UNII: 08H094218D)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
ALCOHOL (UNII: 3K9958V90M)	

ı	Packaging						
	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
		237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/12/2021				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	04/12/2021				

Labeler - FRUIT OF THE EARTH, INC. (079559467)

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