

BIOSILK- benzalkonium chloride soap
Farouk Systems, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

BioSilk Foam Hand Antibacterial Soap

Inactive ingredients

Inactive ingredients: Aqua, Water/Eau, Sodium C14-16 Olefin Sulfonate, Cocamidopropyl Betaine, Glycerin, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Aloe Barbadensis Leaf Juice, Hydrolyzed Silk, Phenoxyethanol, Caprylyl Glycol, Disodium Laureth Sulfosuccinate, Cetyltrimonium Chloride, Potassium Sorbate, Tetrasodium EDTA, Hexylene Glycol, Alcohol Denat., Citric Acid, Sodium Chloride, Fragrance (Parfum), Limonene, Citral ID: 80-BSHSO

BIOSILK[®]
 HEALTH+CARE
ANTIBACTERIAL
HAND SOAP
 WITH
ALOE VERA & TEA TREE
 FOR SILKY, SOFT HANDS

92% NATURAL

MADE IN THE USA
 5.5 FL OZ (163 mL)

Drug Facts	
Active ingredient	Purpose
Benzalkonium Chloride 0.1%.....	Antibacterial
Use[s]	
<ul style="list-style-type: none"> • For handwashing to decrease bacteria on the skin • Recommended for repeated use 	
Warnings	
<ul style="list-style-type: none"> • For external use only. 	
When using this product	
<ul style="list-style-type: none"> • Do not use in or near eyes • Discontinue use if irritation and redness develop 	
Keep out of reach of children.	
In case of accidental ingestion, seek medical attention or contact Poison Control Center immediately.	
Directions	
<ul style="list-style-type: none"> • Wet hands and forearms • Apply enough product to adequately cover the entire surfaces of the hands and forearms • Scrub thoroughly for at least 30 seconds (include fingernails and cuticles) • Rinse 	
Other information	
<ul style="list-style-type: none"> • Store in a dry cool place below 104°F 	
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NDC 73740-4040-6

Manufactured by / Fabriqué par / Fabricado en EUA por
 Farouk Systems, Inc., Houston, Texas 77090, USA
 EU Responsible Person
CE. Way Regulatory Consultants Ltd.
 Kunavarjeva ulica 9, 1000 Ljubljana, Slovenia
 BIOSILK.COM



Active Ingredient

Active ingredient Purpose

Benzalkonium Chloride 0.1%

Antibacterial

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BSHSO6



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Purpose

Uses

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Recommended for repeated use

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Indications & Usage

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Storage and Handling

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Dosage & Administration

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Principal Display Panel

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92% Natural

MADE IN THE USA
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BIOSILK

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73740-4040
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM (UNII: 7N6JUD5X6 Y) (BENZALKONIUM - UNII:7N6JUD5X6 Y)	BENZALKONIUM	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	0.011 g in 100 g
WATER (UNII: 059QF0K00R)	88.5419 g in 100 g
ANHYDROMETHYLENECITRIC ACID (UNII: 99197U4E9K)	0.001 g in 100 g
LIMONENE, (+)- (UNII: GFD7C86Q1W)	0.1755 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	1.5 g in 100 g
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.0915 g in 100 g
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.001 g in 100 g
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.5 g in 100 g
ETIDRONATE TETRASODIUM (UNII: CZZ9T1T1X4)	0.084 g in 100 g
SILK, ACID HYDROLYZED (1000 MW) (UNII: 8549W658QV)	0.0011 g in 100 g
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.4 g in 100 g
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	0.4 g in 100 g
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	0.2 g in 100 g
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.1 g in 100 g
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	0.05 g in 100 g
CITRAL (UNII: T7EU0O9VPP)	0.033 g in 100 g
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	3.5 g in 100 g
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	4 g in 100 g
DISODIUM LAURETH SULFOSUCCINATE (UNII: D6DH1DTN7E)	0.3 g in 100 g
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	0.01 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73740-4040-6	163 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/31/2020	
2	NDC:73740-4040-1	340 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/31/2020	
3	NDC:73740-4040-5	739 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/31/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/31/2020	

Labeler - Farouk Systems, Inc. (137598132)

Registrant - Faoruk Systems, Inc. (137598132)

Establishment

Name	Address	ID/FEI	Business Operations
Farouk Systems, Inc.		137598132	manufacture(73740-4040)