BIOSILK HAND SANITIZER- alcohol (ethyl alcohol) gel Farouk Systems, 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.

BioSilk Hand Sanitizer

Dosage & Administration

Active ingredient Purpose Ethyl Alcohol 77% v/v Antimicrobial

Use for hand-washing to decrease bacteria on the skin, only when water is not available.



Drug Facts Active ingredient Purpose Ethyl Alcohol 77% v/v Antimicrobial Use for hand-washing to decrease bacteria on the skin, only when water is not available. Warnings Flammable, keep away from fire and flames. For external use only. When using this product do not get into eyes if contact occurs, rinse eyes thoroughly with water Stop use and ask a doctor if: irritation and redness develop Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away Directions wet hands thoroughly with product and allow to dry without wiping for children under 6, use only under adult supervision Other information Do not store at temperatures above 105°F Inactive ingredients Aloe Barbadensis Leaf Extract*, Aqua/Water/Eau, Glycerin, Propanediol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer. Aminomethyl Propanol



Fragrance (Parfum), Citral,
Limonene, Linalool
ID: 80-CHIOGAVHS

*organically grown aloe vera,
certification pending

NDC 73740-2020-2

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

FAROUK
CHI*| BIOSILK*
BSAVHS2

Inactive Ingredients

Inactive ingredients
Aloe Barbadensis Leaf
Extract*, Aqua/Water/Eau,
Glycerin, Propanediol,
Acrylates/C10-30 Alkyl
Acrylate Crosspolymer,
Aminomethyl Propanol,
Fragrance (Parfum), Citral,
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ID: 80-CHIOGAVHS
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Drug Facts

Active ingredient
Ethyl Alcohol 77% v/v____

Purpose Antimicrobial

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Warnings

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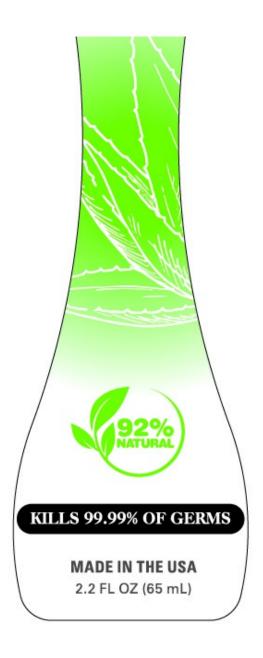
When using this product

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Other information

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Active Ingredients

Active ingredient Purpose Ethyl Alcohol 77% v/v Antimicrobial



Drug Facts

Active ingredient

Purpose

Ethyl Alcohol 77% v/v

Antimicrobial

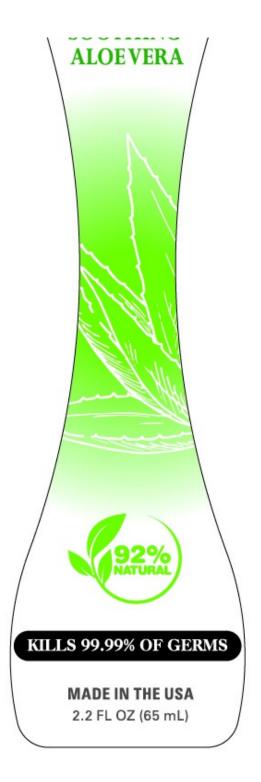
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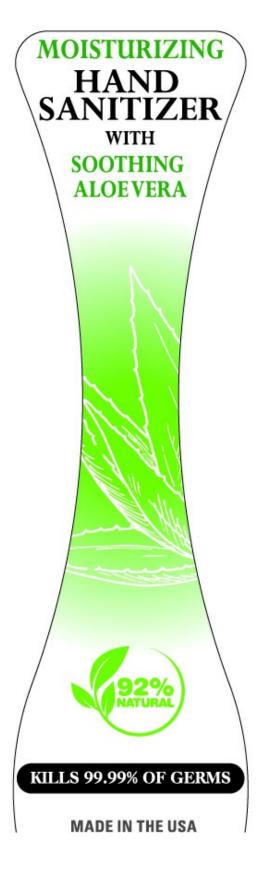
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Route, Methos and Frequency of Administration

Use for hand-washing to decrease bacteria on the skin, only when water is not available.

Directions
wet hands
thoroughly with
product and allow
to dry without
wiping
for children



Drug Facts

Active ingredient

Purpose

Ethyl Alcohol 77% v/v...

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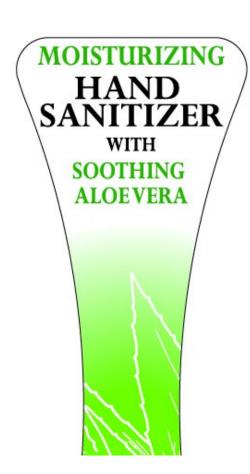
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Warnings and Precautions

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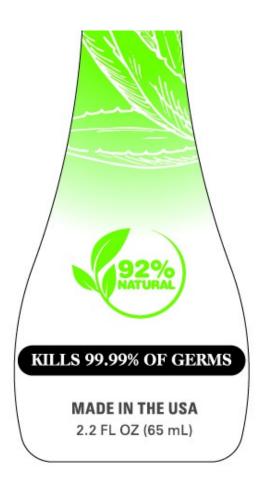
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Storage and Handling

Other information Do not store at temperatures above 105°F



Drug Facts

Active ingredient

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Ethyl Alcohol 77% v/v_

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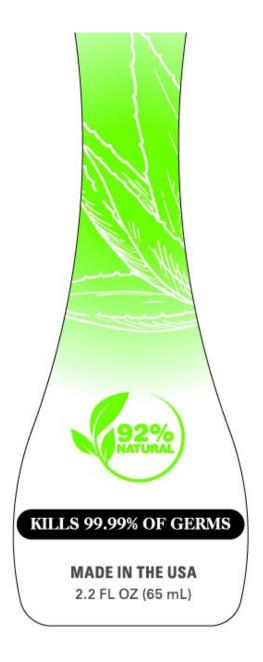
When using this product

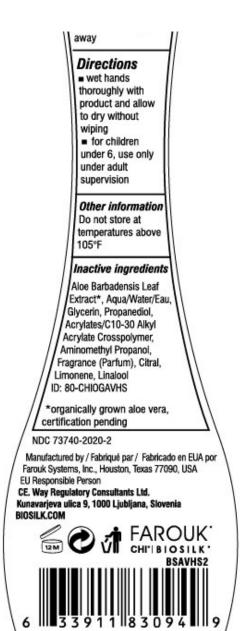
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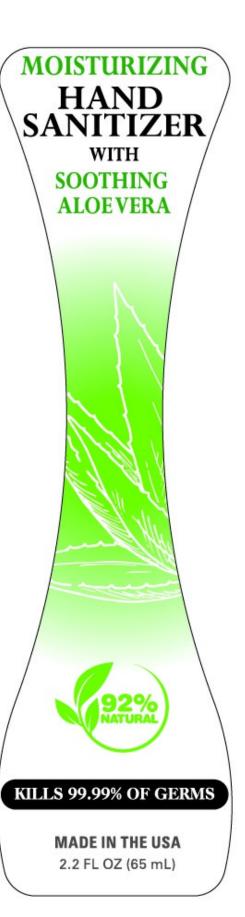




Indications & Usage

Use for hand-washing to decrease bacteria on the skin, only when water is not available.

Directions
wet hands
thoroughly with
product and allow
to dry without
wiping
for children
under 6, use only
under adult
supervision



Drug Facts

Active ingredient

Purpose

Ethyl Alcohol 77% v/v...

Antimicrobial

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Warnings

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Inactive ingredients

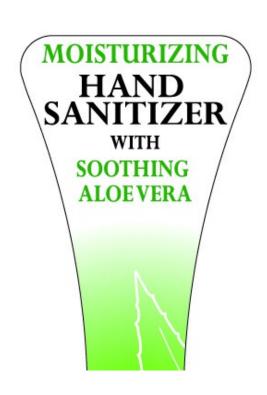
Aloe Barbadensis Leaf Extract*, Aqua/Water/Eau,





OTC - Keep out of reach of Children

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Drug Facts

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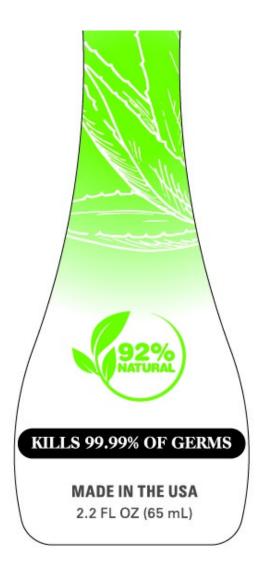
Stop use and ask a doctor if:

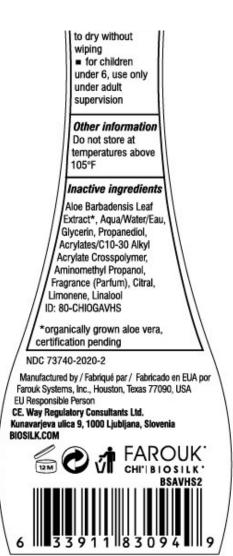
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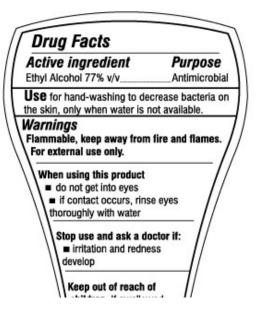


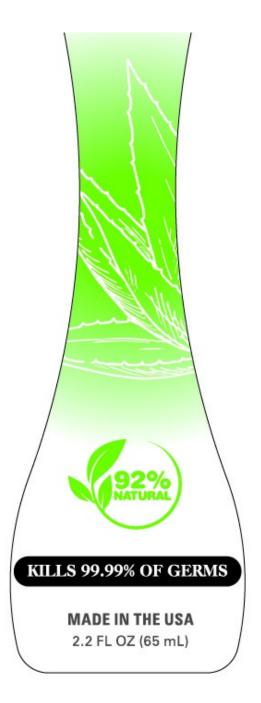


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Principal Display Panel

BioSilk

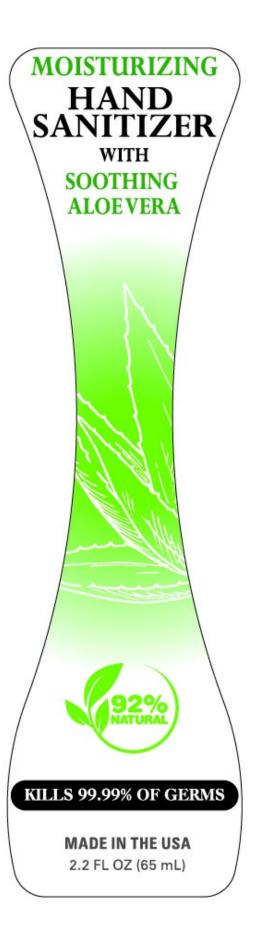
Moisturizing Hand Sanitizer'
With Soothing Aloe Vera

92% Natural

KILLS 99.99% OF GERMS

MADE IN THE USA

2.2 FL OZ (65 mL)



Drug Facts

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BIOSILK HAND SANITIZER

alcohol (ethyl alcohol) gel

D 1 .	T C
Product	Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73740-2020

Route of Administration CUTANEOUS

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	77 g in 100 g	

Inactive Ingredients				
Ingredient Name	Strength			
CITRAL (UNII: T7EU0O9VPP)	0.0275 g in 100 g			
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	0.095 g in 100 g			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	28.5 g in 100 g			
PROPANEDIOL (UNII: 5965N8W85T)	2 g in 100 g			
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.0715 g in 100 g			
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	0.4 g in 100 g			
LINALOOL, (+)- (UNII: F4VNO44C09)	0.00475 g in 100 g			
WATER (UNII: 059QF0KO0R)	6.255 g in 100 g			
GLYCERIN (UNII: PDC6A3C0OX)	2 g in 100 g			
LIMO NENE, (+)- (UNII: GFD7C86Q1W)	0.14625 g in 100 g			

Product Characteristics			
Color	Score		
Shape	Size		
Flavor	Imprint Code		
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73740-2020- 2	65 g in 1 BOTTLE; Type 0: Not a Combination Product	03/18/2020	
2	NDC:73740-2020- 5	159 g in 1 BOTTLE; Type 0: Not a Combination Product	03/18/2020	
3	NDC:73740-2020- 1	354 g in 1 BOTTLE; Type 0: Not a Combination Product	03/18/2020	
4	NDC:73740-2020- 0	208198 g in 1 DRUM; Type 0: Not a Combination Product	04/06/2020	
5	NDC:73740-2020-	59 g in 1 BOTTLE; Type 0: Not a Combination Product	04/09/2020	
6	NDC:73740-2020-	3785 g in 1 JUG; Type 0: Not a Combination Product	04/09/2020	
	NIDC -72740 2020	10.410.00 a in 1.CONTAINED. Type 0. Not a Combination		

7		Product	04/30/2020	
8	NDC:73740-2020- 7	355 g in 1 BOTTLE; Type 0: Not a Combination Product	04/02/2020	
9	NDC:73740-2020- 6	177 g in 1 BOTTLE; Type 0: Not a Combination Product	03/18/2020	





Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/18/2020	

Labeler - Farouk Systems, Inc. (137598132)

$\pmb{Registrant - } \textit{Farouk Systems, Inc. (137598132)}$

Establishment				
Name	Address	ID/FEI	Business Operations	
Farouk Systems, Inc.		137598132	manufacture(73740-2020)	

Revised: 9/2020 Farouk Systems, Inc.