

BIOSILK- alcohol (ethyl alcohol) spray
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 Spray

Dosage & Administration

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

<p>BIOSILK®</p> <p>MOISTURIZING</p> <p>HAND</p> <p>2</p> <p>SANITIZER</p> <p>SPRAY</p> <p>WITH</p> <p>ALCOHOL & PEROXIDE</p>  <p>ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION</p> <p>HAND SANITIZER • NON-STERILE SOLUTION</p> <p>KILLS 99.99% OF GERMS</p> <p>MADE IN THE USA 2 FL OZ (59 mL)</p>	<table border="1"> <tr> <th colspan="2">Drug Facts</th> </tr> <tr> <th>Active ingredient[s]</th> <th>Purpose</th> </tr> <tr> <td>Alcohol 80% v/v</td> <td>Antiseptic</td> </tr> <tr> <th colspan="2">Use[s]</th> </tr> <tr> <td colspan="2">Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</td> </tr> <tr> <th colspan="2">Warnings</th> </tr> <tr> <td colspan="2">For external use only. Flammable. Keep away from heat or flame.</td> </tr> <tr> <th colspan="2">Do not use</th> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds </td> </tr> <tr> <th colspan="2">When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</th> </tr> <tr> <th colspan="2">Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</th> </tr> <tr> <th colspan="2">Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.</th> </tr> <tr> <th colspan="2">Directions</th> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing. </td> </tr> <tr> <th colspan="2">Other information</th> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) </td> </tr> <tr> <th colspan="2">Inactive ingredients: Glycerin, Hydrogen Peroxide, Purified Water</th> </tr> <tr> <th colspan="2">USP ID:80-BSHNS</th> </tr> </table> <p>NDC 73740-3030-2</p> <p>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</p>   <p>BSHNS2</p> 	Drug Facts		Active ingredient[s]	Purpose	Alcohol 80% v/v	Antiseptic	Use[s]		Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.		Warnings		For external use only. Flammable. Keep away from heat or flame.		Do not use		<ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds 		When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.		Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.		Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.		Directions		<ul style="list-style-type: none"> • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing. 		Other information		<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 		Inactive ingredients: Glycerin, Hydrogen Peroxide, Purified Water		USP ID:80-BSHNS	
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 USP ID:80-BSHNS

BIOSILK®

MOISTURIZING

HAND

2

SANITIZER

SPRAY

WITH

ALCOHOL & PEROXIDE



ALCOHOL ANTISEPTIC 80%
TOPICAL SOLUTION
HAND SANITIZER • NON-STERILE SOLUTION

KILLS 99.99% OF GERMS

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2 FL OZ (59 mL)

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BSHNS2



6 33391183132 8

Active Ingredient

Active ingredient[s] Purpose

Alcohol 80% v/v.....Antiseptic

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Storage and Handling

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MOISTURIZING

HAND

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BSHNS2 6 3391183132 8

Indications & Usage

Active ingredient[s] Purpose

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Principal Display Panel

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BIOSILK

alcohol (ethyl alcohol) spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73740-3030
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	18.425 g in 100 g
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	1.45 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73740-3030-2	59 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/27/2020	
2	NDC:73740-3030-8	237 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/27/2020	
3	NDC:73740-3030-9	3785 g in 1 JUG; Type 0: Not a Combination Product	04/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/27/2020	

Labeler - Farouk Systems, Inc. (137598132)

Registrant - Farouk Systems, Inc. (137598132)

Establishment

Name	Address	ID/FEI	Business Operations
Farouk Systems, Inc.		137598132	manufacture(73740-3030)

Revised: 4/2020

Farouk Systems, Inc.