# 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.

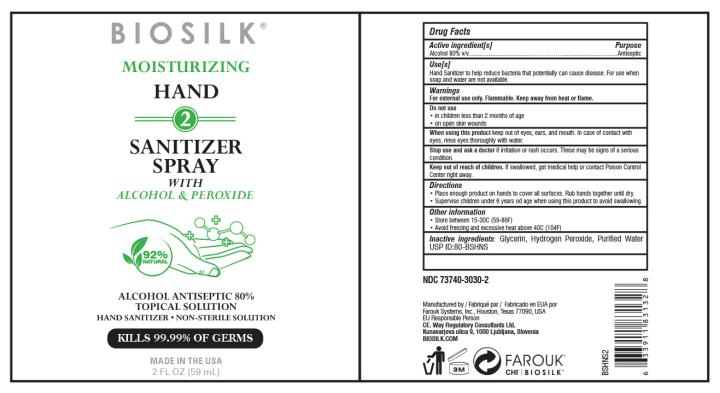
-----

## **BioSilk Hand Sanitizer Spray**

# **Dosage & Administration**

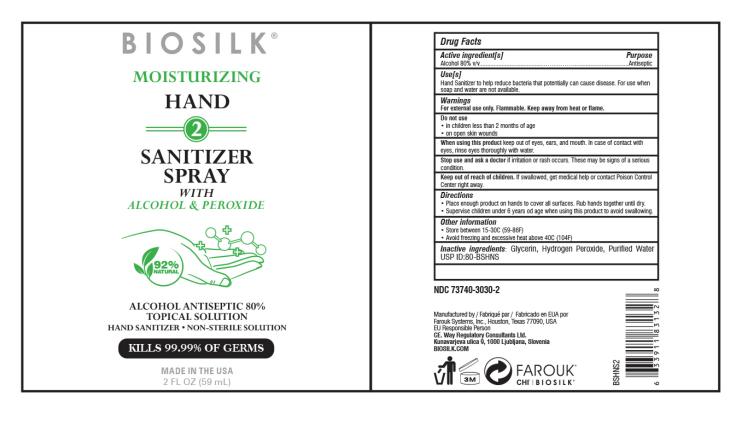
Directions

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



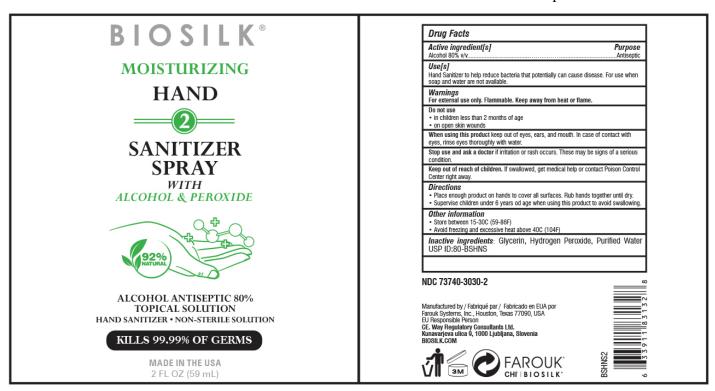
### **Inactive Ingredients**

Inactive ingredients: Glycerin, Hydrogen Peroxide, Purified Water USP ID:80-BSHNS



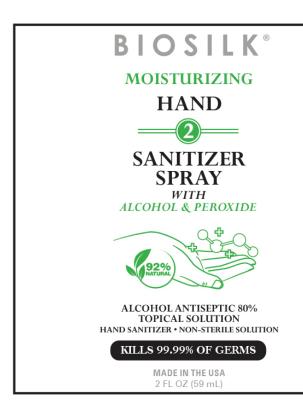
# **Active Ingredient**

Active ingredient[s] Purpose Alcohol 80% v/v......Antiseptic



## Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.



# Drug Facts Active ingredient[s] Alcohol 80% v/v..... Purpose Antiseptic 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 • 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 seriou Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away. Directions Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years od age when using this product to avoid swallowing Other information • 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 NDC 73740-3030-2 Manufactured by / Fabriqué par / Fabricado en EUA por Farouk Systems, Inc., Houston, Texas 77090, USA EU Responsible Person CE. Way Regulatory Consultants Ltd. Kunavarjeva utica 9, 1000 Ljubljana, Slovenia BIOSILK.COM

FAROUK"

CHIBIOSILK

BSHNS2

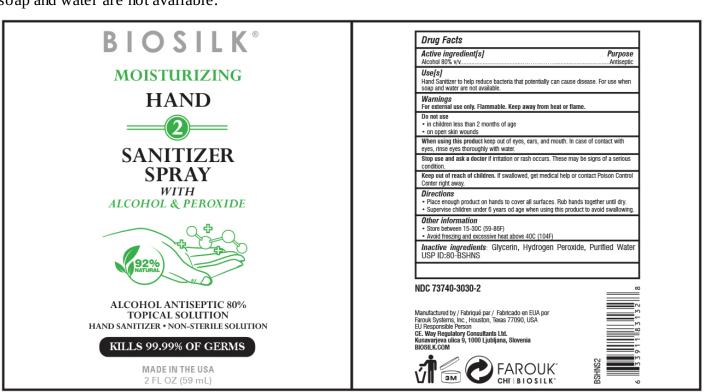
3M

#### **Purpose**

Active ingredient[s] Purpose
Alcohol 80% v/v......Antiseptic

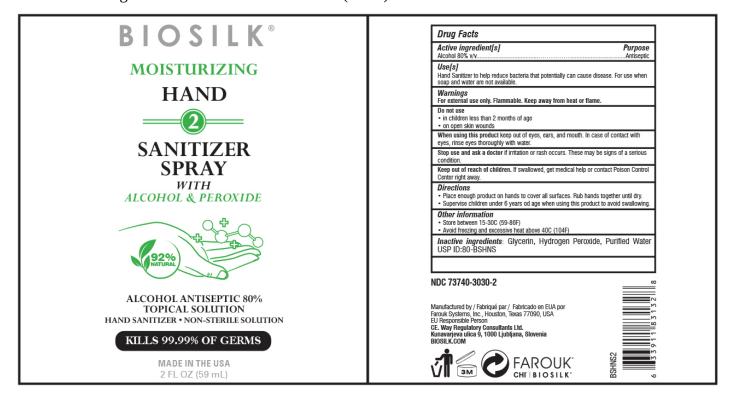
# Use[s]

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.



# Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)



# **Warnings**

Warnings

For external use only. Flammable. Keep away from heat or flame.

Do not use

- 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.



# Drug Facts Active ingredient[s] Alcohol 80% v/v..... Purpose Antiseptic 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 • 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 seriou Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away. Directions Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years od age when using this product to avoid swallowing Other information • 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 NDC 73740-3030-2 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.C

FAROUK"

CHIBIOSILK

зм

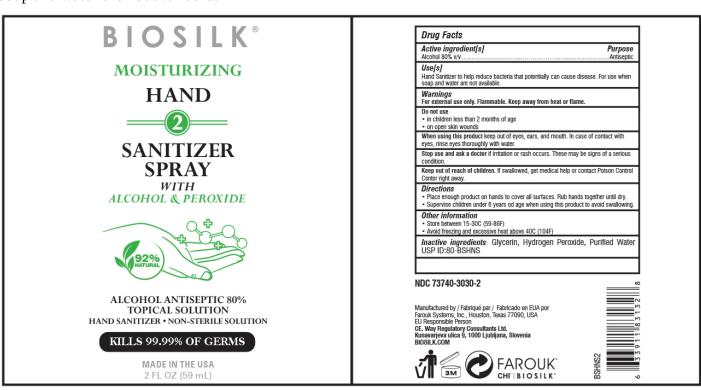
BSHNS2

### **Indications & Usage**

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.



**BioSilk** 

**MOISTURIZING** 

**HAND** 

**SANITIZER** 

SPRAY

WITH

ALCOHOL & PEROXIDE

ALCOHOL ANTISEPTIC 80%

TOPICAL SOLUTION

HAND SANITIZER • NON-STERILE SOLUTION

KILLS 99.99% OF GERMS

92%

MADE IN THE USA

2 FL OZ (59 mL)



#### **MOISTURIZING**

# HAND



WITH ALCOHOL & PEROXIDE



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

#### KILLS 99.99% OF GERMS

MADE IN THE USA 2 FL OZ (59 mL)

#### Drug Facts

Active ingredient[s]
Alcohol 80% v/v.....

Purpose

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
   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 will eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serio

Keep out of reach of children. If swallowed, get medical help or contact Poison Contro Center right away.

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

### Other information

- 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

#### NDC 73740-3030-2

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









# **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

8			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)	18.425 g in 100 g		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 g in 100 g		
GLYCERIN (UNII: PDC6A3C0OX)	1.45 g in 100 g		

F	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.