GAIA HERBS HAND SANITIZER- alcohol solution GAIA HERBS ANTISEPTIC HAND RUB- alcohol solution Gaia Herbs, 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.

Gaia Hand Sanitizer / Antiseptic Hand Rub

Drug Facts

Active ingredient

Alcohol 80% v/v

Purpose

Antiseptic

Use

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

ANTISEPTIC HAND RUB: Healthcare personnel hand rub to help reduce bacteria that potentially can cause disease.

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 a 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 of age when using this product to avoid swallowing.

Other information

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Gaia Herbs, Inc.

101 Gaia Herbs Drive

Brevard, NC 28712

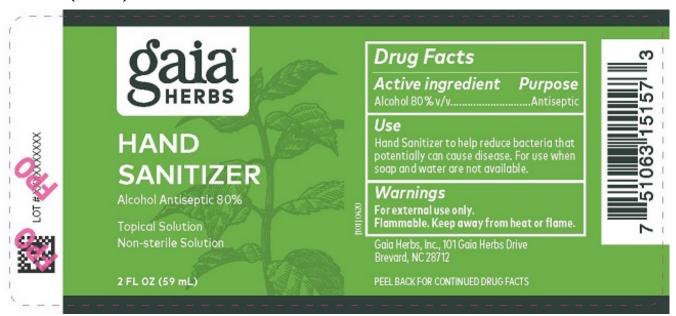
gaia® HERBS

HAND SANITIZER

Alcohol Antiseptic 80%

Topical Solution

2 FL OZ (59 mL)



80010420

Drug Facts (continued)

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- · in children less than 2 months of age
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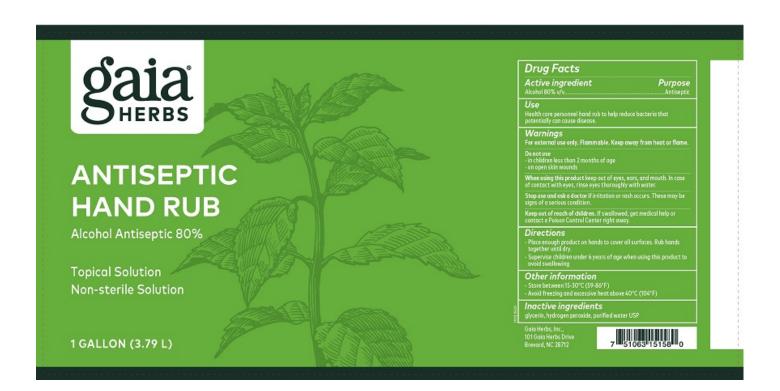
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Gaia Herbs, Inc., 101 Gaia Herbs Drive Brevard, NC 28712

gaia® HERBS ANTISEPTIC HAND RUB

Alcohol Antiseptic 80% Topical Solution Non-Sterile Solution 1 GALLON (3.79 L)



GAIA HERBS HAND SANITIZER

alcohol solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:74817-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients			
Ingredient Name	Strength		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)			
GLYCERIN (UNII: PDC6 A3C0 OX)			
WATER (UNII: 059QF0KO0R)			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:74817-001- 02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/21/2020	

GAIA HERBS ANTISEPTIC HAND RUB

alcohol solution

D 1 4	Information
Product	Intormation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:74817-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL 80 L in 100 L

Inactive Ingredients

8		
Ingredient Name	Strength	
HYDROGEN PERO XIDE (UNII: BBX060AN9V)		
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		

Packaging

l	# Item Code Package Description		Marketing Start Date	Marketing End Date	
ı	1	NDC:74817-002-01	3.79 L in 1 JUG; Type 0: Not a Combination Product	04/21/2020	

Marketing Information

True meeting rimor military			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/21/2020	

Labeler - Gaia Herbs, Inc (623101664)

Establishment			
Name	Address	ID/FEI	Business Operations
Gaia Herbs, Inc		623101664	manufacture (748 17-001, 748 17-002)

Revised: 4/2020 Gaia Herbs, Inc