

BOTANIF HAND SANITIZER- alcohol spray
GAXTRACTS LLC

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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

3000 mL NDC: 74618-201-9355



59 mL NDC: 74618-201-02

Drug Facts

Active Ingredient:

Ethyl Alcohol 80% v/v

Purpose:

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

- In children less than 2 months of age
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Directions

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Other information

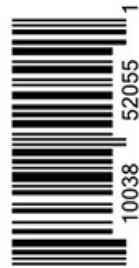
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)
- Non-Sterile Solution

Inactive ingredients glycerin, hydrogen peroxide, purified water USP, non-sterile solution

80% ALCOHOL

Botanif™

HAND SANITIZER



- ✓ Spray enough to cover hands
- ✓ Rub together until dry
- ✓ Supervise children when using



Ethyl Alcohol - 2 FL OZ (59 mL)
NDC# 74618-201-02

Distributed by
GaXtracts, LLC
Union Point, GA 30669
www.botanif.com



118 mL NDC: 74618-201-04

Drug Facts	
Active Ingredient: Ethyl Alcohol 80% v/v.....	Purpose: 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 • 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 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) • Non-Sterile Solution	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP, non-sterile solution	

80% ALCOHOL

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HAND SANITIZER




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- ✓ Spray enough to cover hands
- ✓ Rub together until dry
- ✓ Supervise children when using



Ethyl Alcohol – 4 FL OZ (118 mL)
NDC# 74618-201-04

236.6 mL NDC: 74618-201-08

Drug Facts	
Active Ingredient: Ethyl Alcohol 80% v/v.....	Purpose: Antimicrobial
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 • 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.	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP, non-sterile solution	

80% ALCOHOL

Botanif™

the professional advantage

HAND SANITIZER

Antiseptic Topical Solution




Made in Georgia with Sustainable Processes
gaxtracts.com



- ✓ Spray enough to cover hands
- ✓ Rub together until dry
- ✓ Supervise children when using



Ethyl Alcohol – 8 FL OZ (236.6mL)
NDC 74618-201-08

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 15-30C (59-86F)
• Avoid freezing and excessive heat above 40C (104F)
• Non-Sterile Solution

354.9 mL NDC: 74618-201-12

Drug Facts

Active Ingredient: Ethyl Alcohol 80% v/v.....
Purpose: 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
• 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.

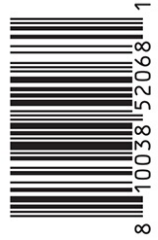
Other information • Store between 15-30C (59-86F)
• Avoid freezing and excessive heat above 40C (104F)
• Non-Sterile Solution

Inactive ingredients glycerin, hydrogen peroxide, purified water USP, non-sterile solution

80% ALCOHOL

Botanif™

HAND SANITIZER



- ✓ Spray enough to cover hands
- ✓ Rub together until dry
- ✓ Supervise children when using



Ethyl Alcohol - 12 FL OZ (354.9 mL)
NDC# 74618-201-12

Distributed by
GoXtracts, LLC
Union Point, GA 30669
www.botanif.com



473.2 mL NDC: 74618-201-16

Drug Facts

Active Ingredient: Ethyl Alcohol 80% v/v.....
Purpose: 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
• 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.

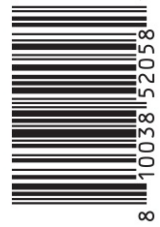
Other information • Store between 15-30C (59-86F)
• Avoid freezing and excessive heat above 40C (104F)
• Non-Sterile Solution

Inactive ingredients glycerin, hydrogen peroxide, purified water USP, non-sterile solution

80% ALCOHOL

Botanif™

HAND SANITIZER



- ✓ Spray enough to cover hands
- ✓ Rub together until dry
- ✓ Supervise children when using
- ✗ Not recommended for some wood surfaces



Ethyl Alcohol - 16 FL OZ (473.2mL)
NDC# 74618-201-16

Distributed by
GaXtracts, LLC
Union Point, GA 30669
www.botanif.com



Pure. Tested. Proven.

3785 mL NDC: 74618-201-99

Drug Facts

Active Ingredient: Ethyl Alcohol 80% v/v.....
Purpose: 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
• 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.

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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 15-30C (59-86F)
• Avoid freezing and excessive heat above 40C (104F)
• Non-Sterile Solution

Inactive ingredients glycerin, hydrogen peroxide, purified water USP, non-sterile solution

80% ALCOHOL

Botanif™

HAND
SANITIZER

Antiseptic Topical Solution



- ✓ Apply enough to cover hands
- ✓ Rub together until dry
- ✓ Supervise children when using
- ✗ Not recommended for some wood surfaces

Ethyl Alcohol - NET 1 GAL (3.78 L)
NDC# 74618-201-99



Pure. Tested. Proven.

Distributed by
GaXtracts, LLC
Union Point, GA 30669
www.botanif.com



BOTANIF HAND SANITIZER

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74618-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74618-201-02	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/23/2020	
2	NDC:74618-201-04	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/23/2020	
3	NDC:74618-201-08	236.6 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/23/2020	
4	NDC:74618-201-16	473 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/23/2020	
5	NDC:74618-201-99	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2020	
6	NDC:74618-201-93	3000 mL in 1 BOX; Type 0: Not a Combination Product	06/01/2020	
7	NDC:74618-201-12	354.9 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/23/2020	

Labeler - GAXTRACTS LLC (065442819)

Establishment

Name	Address	ID/FEI	Business Operations
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GAXTRACTS LLC		065442819	manufacture(74618-201)
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Revised: 9/2020

GAXTRACTS LLC