

BLUESTEM HAND SANITIZER- alcohol liquid
Green Stem, 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

59 mL NDC: 78701-150-01
118 mL NDC: 78701-150-02
236 mL NDC: 78701-150-03
236 mL NDC: 78701-150-04
473 mL NDC: 78701-150-05
946 mL NDC: 78701-150-09
3785 mL NDC: 78701-150-06
18927 mL NDC: 78701-150-07
208175 mL NDC: 78701-150-08



Drug Facts	
Active ingredient(s) 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)	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

BLUESTEM

Alcohol Antiseptic 80%
Topical Solution

HAND SANITIZER

Non-sterile Solution

16 fl oz (473 ml)



Drug Facts

Active Ingredient	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

- 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 5 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

www.bluestemhs.com



Manufactured by:
B. T. O. Distillers
5313 State Route 140
Bethalto, IL 62010



Batch#: 005 / Expiration: 05/2022

BLUESTEM

Alcohol Antiseptic 80%
Topical Solution

HAND SANITIZER

Non-sterile Solution

1 gal (3.785 L)



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

- 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)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP



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BLUESTEM

Alcohol Antiseptic 80%
Topical Solution

HAND SANITIZER

Non-sterile Solution

5 gal (18.927 L)



www.bluestemhs.com

Drug Facts

Active ingredient(s) 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
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Other information
• Store between 15-30C (59-86F)
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP



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B. T. O. Distillers
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BLUESTEM

Alcohol Antiseptic 80%
Topical Solution

HAND SANITIZER

Non-sterile Solution

4 fl oz (118 ml)



www.bluestemhs.com

Drug Facts

Active Ingredient(s) 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

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Inactive ingredients glycerin, hydrogen peroxide, purified water USP



Manufactured by:
B. T. O. Distillers
5313 State Route 140
Bethalto, IL 62010



BLUESTEM

Alcohol Antiseptic 80%
Topical Solution

HAND SANITIZER

Non-sterile Solution



8 fl oz (236 ml)

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

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Do not use

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- on open skin wounds

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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)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

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Batch#: 005 / Expiration: 05/2022

BLUESTEM

Alcohol Antiseptic 80%
Topical Solution

HAND SANITIZER

Non-sterile Solution



32 fl oz (946 ml)

Drug Facts

Active Ingredient	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

- 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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Other Information

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- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

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BLUESTEM HAND SANITIZER

alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:78 70 1-150

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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78701-150-01	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/08/2020	
2	NDC:78701-150-02	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/08/2020	
3	NDC:78701-150-03	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/08/2020	
4	NDC:78701-150-04	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/08/2020	
5	NDC:78701-150-05	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/08/2020	
6	NDC:78701-150-06	3785 mL in 1 JUG; Type 0: Not a Combination Product	06/08/2020	
7	NDC:78701-150-07	18925 mL in 1 PAIL; Type 0: Not a Combination Product	06/08/2020	
8	NDC:78701-150-08	208175 mL in 1 DRUM; Type 0: Not a Combination Product	06/08/2020	
9	NDC:78701-150-09	944 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/08/2020	

Labeler - Green Stem, LLC (117526680)