

LONE STAR BOTANICALS HAND SANITIZER GEL- alcohol gel

LONE STAR BOTANICALS HAND SANITIZER- alcohol solution

Lone Star Botannicals

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.

Lone Star Botannicals Hand Sanitizer

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.

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

Package Label - Principal Display Panel

60ml Gel NDC: 81225-001-01



FRONT

| | |
|---|----------------|
| 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 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: Aloe Vera, Glycerin, *hydroxypropyl cellulose, *hydroxypropyl methylcellulose, Purified Water | |
| *May or may not include | |

BACK

355ml Gel NDC: 81225-001-02



Hand Sanitizer

Alcohol Antiseptic 80%
 (Unscented Aloe Gel)
 Non-Sterile Solution
 12.0 oz (355mL)

Manufactured By:
Huck Diversified Technologies, LLC.
 111 Cash Street
 Jacksonville, TX 75766
 903-339-1257 P/N: LSB-12AG

| | |
|--|----------------|
| 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 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: Aloe Vera, Glycerin, *hydroxypropyl cellulose, *hydroxypropyl methylcellulose, Purified Water | |
| *May or may not include | |

946ml Gel NDC: 81225-001-03



Hand Sanitizer

Alcohol Antiseptic 80%
 (Unscented Aloe Gel)
 Non-Sterile Solution
 32.0 oz (946mL)

Manufactured By:
Huck Diversified Technologies, LLC.
 111 Cash Street
 Jacksonville, TX 75766
 903-339-1257 P/N: LSB-32AG

| | |
|--|----------------|
| 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 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: Aloe Vera, Glycerin, *hydroxypropyl cellulose, *hydroxypropyl methylcellulose, Purified Water | |
| *May or may not include | |

60ml Gel - Scented NDC: 81225-001-04



Hand Sanitizer

Alcohol Antiseptic 80%
(Scented Gel)
Non-Sterile Solution
2.0 oz (60mL)

Manufactured By:
Huck Diversified Technologies, LLC.
 111 Cash Street
 Jacksonville, TX 75766
 903-339-1257 P/N: LSB-2SG

| | |
|---|----------------|
| 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 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: Cinnamon, Clove, Lemon, Eucalyptus, Rosemary, Glycerin, hydroxypropyl cellulose, *hydroxypropyl methylcellulose, Purified Water | |
| *May or may not include | |

355ml Gel - Scented NDC: 81225-001-05



Hand Sanitizer

Alcohol Antiseptic 80%
(Scented Gel)
Non-Sterile Solution
12.0 oz (355mL)

Manufactured By:
Huck Diversified Technologies, LLC.
 111 Cash Street
 Jacksonville, TX 75766
 903-339-1257 P/N: LSB-12SG

| | |
|---|----------------|
| 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 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: Cinnamon, Clove, Lemon, Eucalyptus, Rosemary, Glycerin, hydroxypropyl cellulose, *hydroxypropyl methylcellulose, Purified Water | |
| *May or may not include | |

946ml Gel - Scented NDC: 81225-001-06



Alcohol Antiseptic 80%
(Scented Gel)
Non-Sterile Solution
32.0 oz (946mL)

Manufactured By:
Huck Diversified Technologies, LLC.
 111 Cash Street
 Jacksonville, TX 75766
 903-339-1257 P/N: LSB-32SG

| | |
|---|----------------|
| 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 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: Cinnamon, Clove, Lemon, Eucalyptus, Rosemary, Glycerin, hydroxypropyl cellulose, hydroxypropyl methylcellulose, Purified Water | |
| *May or may not include | |

120ml Spray NDC: 81225-002-01



Alcohol Antiseptic 80%
(Unscented Aloe Spray)
Non-Sterile Solution
4.0 oz (120mL)

Manufactured By:
Huck Diversified Technologies, LLC.
 111 Cash Street
 Jacksonville, TX 75766
 903-339-1257 P/N: LSB-4AS

| | |
|--|----------------|
| 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 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: Aloe Vera, Glycerin, Hydrogen Peroxide, Purified Water | |

120ml Spray - Scented NDC: 81225-002-02



Hand Sanitizer

**Alcohol Antiseptic 80%
(Scented Spray)
Non-Sterile Solution
4.0 oz (120mL)**

Manufactured By:
Huck Diversified Technologies, LLC.
111 Cash Street
Jacksonville, TX 75766
903-339-1257 **P/N: LSB-4SS**

| | |
|---|------------------------------|
| Drug Facts | |
| Active ingredient(s): Alcohol 80% w/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 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: Cinnamon, Clove, Lemon, Eucalyptus, Rosemary, Glycerin, Hydrogen Peroxide, Purified Water | |

LONE STAR BOTANICALS HAND SANITIZER GEL

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:81225-001(NDC:75512-002) |
| 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

| Ingredient Name | Strength |
|--------------------------------------|------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 1.45 L in 100 L |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | 0.125 L in 100 L |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:81225-001-01 | 0.06 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/07/2020 | |
| 2 | NDC:81225-001-02 | 0.355 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/07/2020 | |

| | | | | |
|---|------------------|---|------------|--|
| 3 | NDC:81225-001-03 | 0.946 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/07/2020 | |
| 4 | NDC:81225-001-04 | 0.06 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/07/2020 | |
| 5 | NDC:81225-001-05 | 0.355 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/07/2020 | |
| 6 | NDC:81225-001-06 | 0.946 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/07/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 12/07/2020 | |

LONE STAR BOTANICALS HAND SANITIZER

alcohol solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:81225-002(NDC:75512-001) |
| 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

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:81225-002-01 | 0.12 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/07/2020 | |
| 2 | NDC:81225-002-02 | 0.12 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/07/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 12/07/2020 | |

Labeler - Lone Star Botannicals (095720972)

Registrant - Lone Star Botannicals (095720972)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|--|
| LONE STAR BOTANICALS | | 095720972 | repack(8 1225-001, 8 1225-002) , label(8 1225-001, 8 1225-002) |

Revised: 12/2020

Lone Star Botannicals