

HAND SANITIZER- alcohol gel
Hidden Springs Manufacturing 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.

Active Ingredient(s)

Alcohol 70% 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

- on 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

water, glycerin, carbomer, propylene glycol, squalane, fragrance, aloe barbadensis leaf juice, tocopheryl acetate

Package Label - Principal Display Panel

010 mL NDC: 78614-435-10

NDC:78614-435-10



FreshTM Hands



70%
Alcohol



Gel



Aloe +
Squalane



Paraben
Free



Dye Free
Formula

Antibacterial Hand Sanitizer Pen

10mL e

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.

INGREDIENTS

ACTIVE: Alcohol [70%] v/v

INACTIVE: Water (Aqua, Eau), Glycerin, Carbomer, Propylene Glycol, Squalane, Fragrance (Parfum), Aloe Barbadensis Leaf Juice, Tocopheryl Acetate

WARNING

For external use only. Flammable. Keep away from heat or flame. Do not use on children less than 2 months of age or on open skin wounds.

IP-FHG10ML / PK-L-FH10MLG



030 mL NDC: 78614-435-30



050 mL NDC: 78614-435-50



Fresh™
Hands

antibacterial
**Hand
Sanitizer**



70%
Alcohol



Gel



Aloe +
Squalane

1.6 US fl oz e 50mL

NDC:78614-435-50

PK-L-HSANG50MLC REV200624

Drug Facts

Active ingredient

Alcohol [70%] 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**
- on 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)

Inactive ingredients

Water (Aqua, Eau), Glycerin, Carbomer, Propylene Glycol, Squalane, Fragrance (Parfum), Aloe Barbadosensis Leaf Juice, Tocopheryl Acetate

Distributed by: FRESH HANDS
USA MADE • FreshHands.com

IP-HSANG50MLC



0 14895 01220 8

118 mL NDC: 78614-435-04

| | |
|--|------------------------------|
| Drug Facts | |
| Active ingredient Alcohol (70%) 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 • on 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 Water (Aqua, Eau), Glycerin, Carbomer, Propylene Glycol, Squalane, Fragrance (Parfum), Aloe Barbardensis Leaf Juice, Tocopheryl Acetate | |

Distributed by: FRESH HANDS • FreshHands.com
NDC: 78614-435-04
IP-FHG4



0 14895 01221 5

PK-L-FH4G

REV200615



Fresh Hands™

antibacterial Hand Sanitizer

- 
70% Alcohol
- 
Gel
- 
Aloe + Squalane
- 
Paraben Free
- 
Dye Free Formula

4 US fl oz e 118mL



473 mL NDC: 78614-435-16

| | | |
|--|--|------------------------------|
| Distributed by: FRESH HANDS • FreshHands.com NDC: 78614-435-16 IP-FHG4 0 14895 01224 6 PK-L-HSANG16-2 REV200619 | Drug Facts | Purpose Antiseptic |
| | Active ingredient Alcohol (70%) v/v | |
| | 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 • on 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 Water (Aqua, Eau), Glycerin, Carbomer, Propylene Glycol, Squalane, Fragrance (Parfum), Aloe Barbardensis Leaf Juice, Tocopheryl Acetate | | |



- 
70% Alcohol
- 
Gel
- 
Aloe + Squalane
- 
Paraben Free
- 
Dye Free Formula



Fresh Hands™

antibacterial
Hand Sanitizer

16 US fl oz e 473mL



- 
70% Alcohol
- 
Gel
- 
Aloe + Squalane
- 
Paraben Free
- 
Dye Free Formula



Fresh Hands™

antibacterial
Hand Sanitizer

16 US fl oz e 473mL

Drug Facts

Active ingredient Alcohol (70%) 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 • on 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

Water (Aqua, Eau), Glycerin, Carbomer, Propylene Glycol, Squalane, Fragrance (Parfum), Aloe Barbadensis Leaf Juice, Tocopheryl Acetate

Distributed by: FRESH HANDS • FreshHands.com
NDC: 78614-435-16
IP-HSANG16FT



PK-L-HSANG16-1 REV200619



Fresh Hands™



antibacterial

Hand Sanitizer



70% Alcohol



Gel



Aloe + Squalane



Paraben Free



Dye Free Formula

16 US fl oz e 473mL

1892 mL NDC: 78614-435-64



Fresh™ Hands

antibacterial Hand Sanitizer



70%
Alcohol



Gel



Aloe +
Squalane



Paraben
Free



Dye Free
Formula

Distributed by: FRESH HANDS • FreshHands.com

Active Ingredient

Alcohol [70%] v/v.....

Purpose

Antiseptic

Use as hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warning for external use only. Flammable. Keep away from heat or flame. **Do not use** • on 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: Water (Aqua, Eau), Glycerin, Carbomer, Propylene Glycol, Squalane, Fragrance (Parfum), Aloe Barbadosensis Leaf Juice, Tocopheryl Acetate

USA MADE PK-L-HSANG64/REV200616

NDC: 78614-435-64

Half Gallon e 1.8L

IP-HSANG64



236 mL NDC: 78614-435-08

ANTIBACTERIAL HAND SANITIZER

Drug Facts

| Active ingredient | Purpose |
|-------------------|------------|
| Alcohol [70%] w/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**
- on 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

Water (Aqua, Eau), Glycerin, Carbomer, Propylene Glycol, Squalane, Fragrance (Parfum), Aloe Barbadosensis Leaf Juice, Tocopheryl Acetate

Distributed by: FRESH HANDS • FreshHands.com

NDC:78614-435-08

IP-HSANG8



PK-L-HSANG8B
REV200619



FreshTM Hands

antibacterial

Hand Sanitizer



70%
Alcohol



Gel



Aloe +
Squalane



Paraben
Free



Dye Free
Formula

8 US fl oz e 236mL



3785 mL NDC: 78614-435-28



Fresh
Hands™

antibacterial

Hand Sanitizer



70%
Alcohol



Gel



Aloe +
Squalane



Paraben
Free



Dye Free
Formula

1 Gallon e (3.79 L)



USA MADE

Drug Facts

Active ingredient

Alcohol [70%] v/vAntiseptic

Purpose

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**
- on 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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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

Water (Aqua, Eau), Glycerin, Carbomer, Propylene Glycol, Squalane, Fragrance (Parfum), Aloe Barbadosensis Leaf Juice, Tocopheryl Acetate

Distributed by: FRESH HANDS
FreshHands.com
NDC: 78614-435-28
IP-HSANG128



PK-L-HSANG128 REV200616

HAND SANITIZER

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78614-435 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 70 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 1.45 mL in 100 mL |
| WATER (UNII: 059QF0K00R) | |
| SQUALANE (UNII: GW89575KF9) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:78614-435-10 | 10 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 03/30/2020 | |
| 2 | NDC:78614-435-30 | 30 mL in 1 TUBE; Type 0: Not a Combination Product | 03/30/2020 | |
| 3 | NDC:78614-435-50 | 50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |
| 4 | NDC:78614-435-04 | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |
| 5 | NDC:78614-435-16 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |
| 6 | NDC:78614-435-64 | 1892.71 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 03/30/2020 | |
| 7 | NDC:78614-435-08 | 236.59 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 03/30/2020 | |
| 8 | NDC:78614-435-28 | 3785.41 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 03/30/2020 | |

Labeler - Hidden Springs Manufacturing LLC. (122841764)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|------------------------------|---------|-----------|------------------------|
| HIDDEN SPRINGS MFG., CO. LLC | | 122841764 | manufacture(78614-435) |

Revised: 6/2020

Hidden Springs Manufacturing LLC.