

ALCOHOL ANTISEPTIC HAND SANITIZER NON-STERILE SOLUTION- alcohol gel
Pegasus Biotechnology 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.

Alcohol Antiseptic Hand Sanitizer Non-Sterile Solution

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

Directions

- Place enough product on hands to cover all surfaces. Rub hands together continuously until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

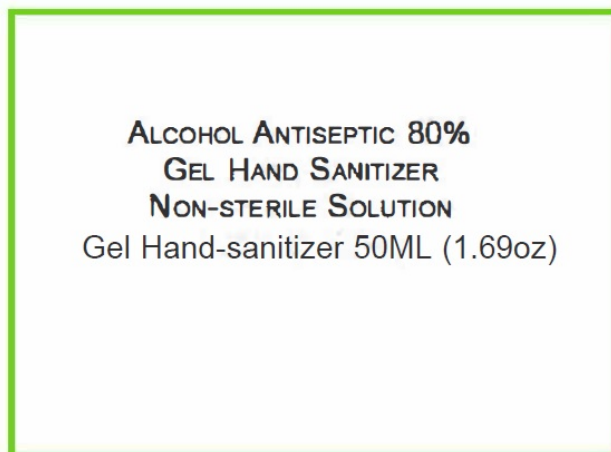
Other information

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

Inactive ingredients

Aloe Vera, Vitamin E, Carbomer, TEA, Deionized Water, Fragrance, fd&c blue no.1

Package Labeling:50 ml



| | |
|---|------------------------------|
| 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 <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• Place enough product on hands to cover all surfaces. Rub hands together continuously until dry.• Supervise children under 6 years of age when using this product to avoid swallowing. | |
| Other information <ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F) | |
| Inactive ingredients Aloe Vera, Vitamin E, Carbomer, TEA, Deionized Water, Fragrance, fd&c blue no.1 | |

DISTRUBUTED BY:
PEGASUS BIOTECHNOLOGY, LLC
911 EAST BRANDON BLVD
BRANDON, FL 333511

Package Labeling:100 ml

ALCOHOL ANTISEPTIC 80%
 GEL HAND SANITIZER
 NON-STERILE SOLUTION
 GelHand-sanitizer 100ML {3.38oz}

| | |
|---|----------------|
| 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 | |
| <ul style="list-style-type: none"> • 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 | |
| <ul style="list-style-type: none"> • Place enough product on hands to cover all surfaces. Rub hands together continuously until dry. • Supervise children under 6 years of age when using this product to avoid swallowing. | |
| Other information | |
| <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) | |
| Inactive ingredients Aloe Vera, Vitamin E, Carbomer, TEA, Deionized Water, Fragrance, fd&c blue no.1 | |

DISTRUBUTED BY:
 PEGASUS BIOTECHNOLOGY, LLC
 911 EAST BRANDON BLVD
 BRANDON, FL 333511

Package Labeling:250 ml

ALCOHOL ANTISEPTIC 80%
 GEL HAND SANITIZER
 NON-STERILE SOLUTION
 Gel Hand-sanitizer 250ML (8.45oz)

| | |
|---|----------------|
| 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 | |
| <ul style="list-style-type: none"> • 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 | |
| <ul style="list-style-type: none"> • Place enough product on hands to cover all surfaces. Rub hands together continuously until dry. • Supervise children under 6 years of age when using this product to avoid swallowing. | |
| Other information | |
| <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) | |
| Inactive ingredients Aloe Vera, Vitamin E, Carbomer, TEA, Deionized Water, Fragrance, fd&c blue no. 1 | |

DISTRUBUTED BY:
 PEGASUS BIOTECHNOLOGY, LLC
 911 EAST BRANDON BLVD
 BRANDON, FL 333511

Package Labeling:500 ml

ALCOHOL ANTISEPTIC 80%
 GEL HAND SANITIZER
 NON-STERILE SOLUTION
 Gel Hand-sanitizer 500ML (16.91oz)

| | |
|---|----------------|
| 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 | |
| <ul style="list-style-type: none"> • 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 | |
| <ul style="list-style-type: none"> • Place enough product on hands to cover all surfaces. Rub hands together continuously until dry. • Supervise children under 6 years of age when using this product to avoid swallowing. | |
| Other information | |
| <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) | |
| Inactive ingredients Aloe Vera, Vitamin E, Carbomer, TEA, Deionized Water, Fragrance, fd&c blue no.1 | |

DISTRUBUTED BY:
 PEGASUS BIOTECHNOLOGY, LLC
 911 EAST BRANDON BLVD
 BRANDON, FL 333511

Package Labeling: 1000

ALCOHOL ANTISEPTIC 80%
 GEL HAND SANITIZER
 NON-STERILE SOLUTION
 Gel Hand-sanitizer 1000ML (33.81oz)

| | |
|---|----------------|
| 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 | |
| <ul style="list-style-type: none"> • 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 | |
| <ul style="list-style-type: none"> • Place enough product on hands to cover all surfaces. Rub hands together continuously until dry. • Supervise children under 6 years of age when using this product to avoid swallowing. | |
| Other information | |
| <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) | |
| Inactive ingredients Aloe Vera, Vitamin E, Carbomer, TEA, Deionized Water, Fragrance, fd&c blue no. 1 | |

DISTRUBUTED BY:
 PEGASUS BIOTECHNOLOGY, LLC
 911 EAST BRANDON BLVD
 BRANDON, FL 333511

ALCOHOL ANTISEPTIC HAND SANITIZER NON-STERILE SOLUTION

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:80095-000 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M) | ALCOHOL | 0.8 mL in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) | |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | |
| TEA LEAF (UNII: GH42T47V24) | |
| WATER (UNII: 059QF0KO0R) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:80095-000-05 | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/12/2020 | |
| 2 | NDC:80095-000-10 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/12/2020 | |
| 3 | NDC:80095-000-25 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/12/2020 | |
| 4 | NDC:80095-000-50 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/12/2020 | |
| 5 | NDC:80095-000-00 | 1000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/12/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 10/12/2020 | |

Labeler - Pegasus Biotechnology LLC. (121238045)

Revised: 9/2020

Pegasus Biotechnology LLC.