

ANTIBACTERIAL GEL- alcohol gel

Evolve Verde, S.A. de C.V.

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.

Antibacterial Gel

Drug Facts

Active ingredient[s]

Ethyl Alcohol Antiseptic 70%

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, Triethanolamine, Propylene Glycol, Aloe Vera extract, Carbomer and water bidistilled

Package Labeling: (78157-000-01)



ANTIBACTERIAL GEL

Ethyl Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer
Non-sterile Solution

[3785.41 mL]

Highly effective solution to eliminate pathogenic bacteria that cause infections and diseases.

| | |
|---|------------------------------|
| Drug Facts | |
| Active ingredient(s) Ethyl Alcohol Antiseptic 70% | 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 ageon 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 until dry.Supervise children under 6 years of age when using this product to avoid swallowing. | |
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INGREDIENTS

Ethyl Alcohol, Triethanolamine, Propylene Glycol, Aloe Vera extract, Carbomer and water bidistilled.

GHS CLASIFICACION

Hazard statements: H226 Flammable liquid and vapor H302 Harmful if swallowed H320 Causes slight eye irritation.
Precautionary statements - Prevention P210 Keep away from heat, hot surfaces, sparks, open flames and other sources of ignition. No Smoking. P264 Thoroughly wash face, hands and exposed skin areas after handling. P280 Wear eye protection. P403 Store in a well ventilated place. Precautionary statements - Response Eyes Ingestion P301 + P330 + P331 In case of ingestion, rinse mouth. Do not induce vomiting. P305 + P351 + P338, P337 + P313 In case of contact with the eyes: Rinse carefully with water for several minutes. Remove contact lenses, if present and easy. Continue rinsing. If eye irritation persists: consult a doctor. P370 + P378 In case of fire, use water mist for extinction.

Formulated by
BIO BASED SOLUTIONS, S.A. de C.V.
RFC: BBS160217RE5
Cal. Trabajadores Santa Catarina, Nuevo León,
C.P. 66149, MX.



3.78L (1US GAL)

+52 81 2141 0898 - 99

Package Labeling: (78157-000-02)



ANTIBACTERIAL GEL

Ethyl Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer
Non-sterile Solution

[208,198 mL]

Highly effective solution to eliminate pathogenic bacteria that cause infections and diseases.

| | |
|--|----------------|
| Drug Facts | |
| Active ingredient(s) | Purpose |
| Ethyl Alcohol Antiseptic 70% | Antiseptic |
| Uses(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 until dry. Supervise children under 6 years of age when using this product to avoid swallowing. | |
| Other information | |
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Formulated by
BIO BASED SOLUTIONS, S.A. de C.V.
RFC: **BBS160217RES**
Col. Trabajadores Santa Catarina, Nuevo León,
C.P. 66149, MX.



DRUM 55 US Gallon

+52 81 2141 0898 - 99

Package Labeling: (78157-000-03)



ANTIBACTERIAL GEL

Ethyl Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer
Non-sterile Solution

[1,040,000 mL]

Highly effective solution to eliminate pathogenic bacteria that cause infections and diseases.

| | |
|--|-----------------------|
| Drug Facts | |
| Active ingredient(s) Ethyl Alcohol Antiseptic 70% | 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) | |
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RFC: **BBS160217RES**
Col. Trabajadores Santa Catarina, Nuevo León,
C.P. 66149, MX.



TOTE 1040L

+52 81 2141 0898 - 99

ANTIBACTERIAL GEL

alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78 157-000 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 0.7 mL in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:78157-000-01 | 3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/21/2020 | |
| 2 | NDC:78157-000-02 | 208198 mL in 1 DRUM; Type 0: Not a Combination Product | 05/21/2020 | |
| 3 | NDC:78157-000-03 | 1040000 mL in 1 TANK; Type 0: Not a Combination Product | 05/21/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 05/21/2020 | |

Labeler - Evolve Verde, S.A. de C.V. (812855156)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|------------------------|
| Evolve Verde, S.A. de C.V. | | 812855156 | manufacture(78157-000) |

Revised: 5/2020

Evolve Verde, S.A. de C.V.