

## **ORGANIC ANTISEPTIC GEL- alcohol gel**

**Bioagaves de la Costa, 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.*

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### **Active Ingredients**

Organic Ethyl Alcohol 80% v/v

### **Purpose**

Antiseptic

### **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 mouht. 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 (59-86F).
- Avoid freezing and excessive heat above 40°C (104F)

### **INACTIVE INGREDIENTS**

Organic glycerin, carbomer, triethanolamine, purified water USP, organic aloe vera.



**DRUG FACTS**

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**MADE IN MEXICO BY:**

Bioagaves de la Costa SA de CV.  
Av. Niño Obrero #2267,  
Col. Ciudad Industrial,  
Tepic, Nayarit.  
CP 63173  
RFC: BCC091016D88  
Lot Number:

**Questions:**

Best Ground LLC 501 W Broadway  
Suite 800, San Diego CA 92101

**DISTRIBUTED BY:** BEST GROUND USA LLC  
**ORGANIC CERTIFIED BY:** ECOCERT



**ORGANIC ANTISEPTIC GEL**

alcohol gel

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:76598-002 |
| <b>Route of Administration</b> | 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)       |          |
| CARBOMER 940 (UNII: 4Q93RCW27E)   |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) |          |
| TROLAMINE (UNII: 9O3K93S3TK)      |          |
| WATER (UNII: 059QF0K00R)          |          |

**Packaging**

| # | Item Code        | Package Description                                      | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:76598-002-01 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product    | 04/24/2020           |                    |
| 2 | NDC:76598-002-02 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product    | 04/24/2020           |                    |
| 3 | NDC:76598-002-03 | 1000 mL in 1 BOTTLE; Type 0: Not a Combination Product   | 04/24/2020           |                    |
| 4 | NDC:76598-002-04 | 5000 mL in 1 BOTTLE; Type 0: Not a Combination Product   | 04/24/2020           |                    |
| 5 | NDC:76598-002-05 | 20000 mL in 1 PACKAGE; Type 0: Not a Combination Product | 04/24/2020           |                    |
| 6 | NDC:76598-002-06 | 200000 mL in 1 DRUM; Type 0: Not a Combination Product   | 04/24/2020           |                    |
| 7 | NDC:76598-002-07 | 1000000 mL in 1 TANK; Type 0: Not a Combination Product  | 04/24/2020           |                    |
| 8 | NDC:76598-002-08 | 4500 mL in 1 BOTTLE; Type 0: Not a Combination Product   | 04/24/2020           |                    |
| 9 | NDC:76598-002-09 | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product     | 04/24/2020           |                    |

**Marketing Information**

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A                                 | 04/24/2020           |                    |

**Labeler** - Bioagaves de la Costa, S.A. de C.V. (814644548)**Establishment**

| Name                                | Address | ID/FEI    | Business Operations    |
|-------------------------------------|---------|-----------|------------------------|
| Bioagaves de la Costa, S.A. de C.V. |         | 814644548 | manufacture(76598-002) |

Revised: 5/2020

Bioagaves de la Costa, S.A. de C.V.