

## **ORGANIC ANTISEPTIC GEL HAND SANITIZER 80 V/V- 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 can potentially 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 below 110F (43C)
- May discolor certain fabrics or surfaces

### **INACTIVE INGREDIENTS**

Organic aloe vera, glycerin, purified water

**DISTRIBUTED BY:**  
 BEST GROUND USA LLC  
**ORGANIC CERTIFIED BY:** ECOCERT SA  
**MADE IN MEXICO BY:**  
 Biotecnologías de la Costa SA de CV.  
 Av. Nilito Ojeda #2267, Col.  
 Ciudad Industrial, Tepic, Nayarit.  
 CP 63173 RFC: BCO091016048  
**DISTRIBUTED BY:** BEST GROUND USA LLC  
**QUESTIONS:** Best Ground LLC 501  
 W Broadway Suite 800,  
 San Diego, CA 92101  
**LOT NUMBER:**  
**EXP:**

**7 28798 12338 8**

**Drug Facts**

**Active Ingredient(s)** **Purpose**  
 Organic Ethyl 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**  
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 In case of contact with eyes, rinse eyes thoroughly with water.  
 Stop use and seek a doctor if irritation or rash occurs. There 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 below 110°F (43°C)  
 • May discolor certain fabrics or surfaces.

**Inactive Ingredients** Organic aloe vera gel, glycerin, purified water.

## ORGANIC ANTISEPTIC GEL HAND SANITIZER 80 V/V

alcohol gel

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:76598-008 |
| Route of Administration | 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)       |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) |          |
| WATER (UNII: 059QF0KO0R)          |          |

### Packaging

| #                       | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|-------------------------|------------------|--|----------------------|--------------------|
| 1                       | NDC:76598-008-01 | 4 mL in 1 POUCH; 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(76598-008) |

Revised: 7/2020

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