

**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**

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 surface. 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**

Glycerin, carbomer, triethanolamine, purified water USP, aloe vera.



# ANTISEPTIC GEL



**With Aloe Vera**  
Fragrance Free



**Net. Qty. 169.07 fl oz**  
**(5 L).**

#### 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: BCO091016D88  
Lot Number:

#### Questions:

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

**DISTRIBUTED BY: BEST GROUND USA LLC**



## ANTISEPTIC GEL

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76598-001
<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
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76598-001-01	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
2	NDC:76598-001-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
3	NDC:76598-001-03	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
4	NDC:76598-001-04	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
5	NDC:76598-001-05	20000 mL in 1 PACKAGE; Type 0: Not a Combination Product	04/24/2020	
6	NDC:76598-001-06	200000 mL in 1 DRUM; Type 0: Not a Combination Product	04/24/2020	
7	NDC:76598-001-07	1000000 mL in 1 TANK; Type 0: Not a Combination Product	04/24/2020	
8	NDC:76598-001-08	4500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
9	NDC:76598-001-09	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(76598-001)

Revised: 5/2020

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