

ORGANIC GEL HAND SANITIZER 70 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.

Active Ingredients

Ethyl Alcohol 70% 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 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.



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



ORGANIC GEL HAND SANITIZER 70 V/V

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76598-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALOE VERA LEAF (UNII: ZY8 1Z83H0 X)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76598-005-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
2	NDC:76598-005-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
3	NDC:76598-005-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
4	NDC:76598-005-05	1000 mL in 1 PACKAGE; Type 0: Not a Combination Product	04/24/2020	
5	NDC:76598-005-06	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
6	NDC:76598-005-07	1000000 mL in 1 TANK; Type 0: Not a Combination Product	04/24/2020	
7	NDC:76598-005-08	20000 mL in 1 DRUM; Type 0: Not a Combination Product	04/24/2020	
8	NDC:76598-005-09	200000 mL in 1 TANK; Type 0: Not a Combination Product	04/24/2020	
9	NDC:76598-005-10	5000 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(76598-005)

Revised: 6/2020

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