ANTISEPTIC 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 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 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.





Net. Qty. 60mL

DRUG FACTS Active Ingredients: Alcohol 70% v/v Purpose: Antiseptic

USE Hand senitizer to help reduce bacteria that potencially can cause disease. For use when soop and water are not available.

WARNENGS: For external use only. Keep every from heat or fleme. DO NOT USE: "In children less than 2 months. "On open skin wounds. When using this product keep out of eyes, east and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Stop use and ask a doctor if inflation or rash occurs. These may be signs of a serious condition. Keep out of reach of children, if swellowed, get medical help or contact a Poison Control. Center right ewey.

DIRECTIONS: Place enough product on hands to cover all. surfaces. Rub hands together until dry. Supervise children under ó years of age when using this product to avoid swallowing.

OTHER INFORMATION: Stare between 16° - 30°C (69-86F). Axaid freezing and excessive heat above 40°C (104F).

INACTIVE INGREDIENTS: Gycein, hydrogen perceide, partied water USP MADE IN MEDICO BY: Biregares do la Costa SA de CX Ax. Niño Otrao \$72/67, Col. Curdo Industrial, Roiz, Nayerk C.P. 65173 RFC: BICOVI (NA)OB DISTRIBUTED BY:

BEST GROUND USALLC









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

DRUG FACTS

Active Ingredients: Ethyl Alcohol 70% v/v

Purpose: Antiseptic

Hand sanitizer to help reduce bacteria that potencially can cause disease. For use when soap and water are not available.

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 i mitation 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.

*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.

MADE IN MEXICO BY:

Bioagaves de la Costa SA de CV. Av. Niño Obrero #2267, Col. Cludad 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 USAILC







Net. Qty. 127.817 fl oz (3.78 L).

DRUG FACTS

Active Ingredients: Ethyl Alcohol 70% v/v Purpose: Antiseptic

Hand sanitizer to help reduce bacteria that potencially can cause disease. For use when soap and water are not available.

WARNINGS:

For external use only. Flammable. Keep away from heat or flame.

*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.

MADE IN MEXICO BY: Bioagaves de la Costa SA de CV. Av. Niño Obrero #2267, Col. Ciudad Industrial, Tepic, Nayarit. CP 63173 RFC: BC0091016D88

Lot Number:

Questions: Best Ground LLC 501 W Broadway Suite 800, San Diego CA 92101 DISTRIBUTED BY: BEST GROUND USA LLC



ANTISEPTIC GEL HAND SANITIZER 70 V/V

alcohol gel

Product Information

HUMAN OTC DRUG NDC:76598-004 Product Type Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) 70 mL in 100 mL ALCOHOL

Inactive Ingredients

Ingredient Name	Strength			
TROLAMINE (UNII: 903K93S3TK)				
GLYCERIN (UNII: PDC6A3C0OX)				
CARBOMER 940 (UNII: 4Q93RCW27E)				
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)				
WATER (UNII: 059QF0KO0R)				

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76598-004- 01	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
2	NDC:76598-004- 02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
3	NDC:76598-004- 03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
4	NDC:76598-004- 04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
5	NDC:76598-004- 05	1000 mL in 1 PACKAGE; Type 0: Not a Combination Product	04/24/2020	
6	NDC:76598-004- 06	3785 mL in 1 DRUM; Type 0: Not a Combination Product	04/24/2020	
7	NDC:76598-004- 07	1000000 mL in 1 TANK; Type 0: Not a Combination Product	04/24/2020	
8	NDC:76598-004- 08	20000 mL in 1 DRUM; Type 0: Not a Combination Product	04/24/2020	
9	NDC:76598-004- 09	200000 mL in 1 TANK; Type 0: Not a Combination Product	04/24/2020	
10	NDC:76598-004- 10	4 mL in 1 POUCH; Type 0: Not a Combination Product	09/03/2020	

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.		8 146 44548	manufacture(76598-004)			

Revised: 9/2020 Bioagaves de la Costa, S.A. de C.V.