

ASSURED ALOE- ethyl alcohol gel
4E Global, S.A.P.I. 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 Ingredient Purpose

Ethyl Alcohol 70.0% v/v..... Antimicrobial

Uses

- for handwashing to decrease bacteria on the skin
- recommended for repeated use

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Kills 99% of germs!

Aloe Vera & Moisturizers

Directions

- wet hands thoroughly with product
- briskly rub hands together until dry
- supervise children under 6 years in the use of this product

Warnings

For external use only.

Flammable, keep away from heat and flame.

Do not use in the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.

Inactive Ingredients

water, carbomer, triethanolamine, glycerin, propylene glycol, fragrance, aloe barbadensis leaf juice, fd&c blue no. 1, fd&c yellow no. 5.

Product Label



Drug Facts

Active ingredients.....Purpose
Ethyl Alcohol 70%Antiseptic

Uses ▪ hand sanitizer to help decrease bacteria on the skin. ▪ when water, soap & towel are not available. ▪ recommended for repeated use

Warnings For external use only.

Flammable. Keep away from fire or flame.

Do not apply around eyes. Do not use in ears & mouth

When using this product, avoid contact with eyes. In case of contact flush eyes with water.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

Keep out of reach of children. Children must be supervised in use of this product.

Directions ▪ pump as needed into your palms and thoroughly spread on both hands. ▪ rub into skin until dry.

Other information ▪ store at 20° C (68° to 77° F). ▪ may discolor fabrics.

Inactive ingredients ▪ water, carbomer, triethanolamine, glycerin, propylene glycol, fragrance, aloe barbadensis leaf juice, FD&C blue 1, FD&C yellow 5.

*This product is not manufactured or distributed by Gojo Industries Inc., distributor of the registered trademark Purell®



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DISTRIBUTED BY
GREENBRIER INTERNATIONAL, INC.
500 VOLVO PARKWAY, CHESAPEAKE, VA 23320
MADE IN MEXICO

ASSURED ALOE

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60599-999
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60599-999-10	295 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/27/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/27/2017	

Labeler - 4E Global, S.A.P.I. de C.V (812821307)

Establishment

Name	Address	ID/FEI	Business Operations
4E Global, S.A.P.I. de C.V		812821307	manufacture(60599-999)

Revised: 2/2018

4E Global, S.A.P.I. de C.V