

HAND SANITIZER- ethyl alcohol gel
Ultra Distributors Inc.

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

Ethyl Alcohol 70%

Purpose
Antiseptic

Uses to decrease bacteria on the skin that could cause disease recommended for repeated use

Warnings

for external use only: hands

Flammable. Keep away from fire or flame

When using this product, keep out of eyes. In case of contact with eyes, flush thoroughly with water. avoid contact with broken skin. do not inhale or ingest.

Stop use and ask a doctor if . irritation or redness develops. condition persists for more than 72 hours

Keep out of reach of children. if swallowed, get medical help or contact a poison control center(1-800-222-1222)right away .

Directions

- wet hands thoroughly with product and allow to dry without wiping.
- for children under 6 , use only under adult supervision.
- not recommended for infants .

Other information

- do not store above 105°F
- may discolor some fabrics
- harmful to wood finished and plastics

Inactive ingredients

acrylates/C10-C30 alkyl acrylate crosspolymer,aloe barbadensis leaf juice, aminomethyl propanol, glycerin, maltodextrin, propylene glycol, water , tocopheryl acetate



Instant
Hand Sanitizer
Moisturizing with Vitamin E & Aloe
Instant clean

Kills
99.9%
germs

70% Alcohol
16.9 FL OZ (500mL)

Drug Facts

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Distributed by Ultra Distributors Inc
Somerset Nj 08873, USA

Item No.: 84596



Made in China

HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78495-169
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
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER INTERPOLYMER TYPE A (5500 CPS) (UNII: 59TL3WG5CO)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)

AMINOMETHYLPROPANOL (UNII: LU49E6626Q)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78495-169-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/03/2020	

Labeler - Ultra Distributors Inc. (007160073)

Revised: 6/2020

Ultra Distributors Inc.