ALCOCLEAN HAND SANITIZER- ethyl alcohol gel GADAL Laboratories, 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.

AlcoClean HAND SANITIZER

Drug Facts

Active Ingredient

Ethyl Alcohol 65%

Purpose

Antiseptic

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Inactive Ingredients

Water (Aqua), Aloe Barbadensis Leaf Juice, Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine.

Directions

Put a thumbnail size amount in your palm and rub your hands together briskly until dry. Children under 6 years of age should be supervised when using.

Warning

Flammable. Keep away from flames. Keep out of eyes. In case of eye contact immediately flush eyes with water then contact physician. If swallowed, contact physician. For external use only. Do not store above 110°F.

Keep out of reach of children.

Other Information

Store at room temperature.

Made with 65% Alcohol

Kills **99.9%** of germs!

Eliminates Harmful Bacteria Leaves Hands Feeling Refreshed GOOD MANUFACTURING PRACTICE

GMP

QUALITY PRODUCT

MADE IN THE USA

PCO FOODS

Distributed by: **PCO Foods** 1110 Powers Place Alpharetta, GA, 30009 • pcofoods.com • sales@pcofoods.com

Packaging



 Drug Facts
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 Active Ingredient
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 Warning Flamable. Keep away from flames. Keep out of eyes. In fase abadensis Leaf Juice, Carbomer, Fragrance, Glycain. Propylene Glycol. Tocopheryl Acetate, Triethanolamine.
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 Trocopheryl Acetate, Triethanolamine.
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8 FL OZ (236.5 ML)

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ALCOCLEAN HAND SANITIZER

ethyl alcohol gel

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Product	Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:53113-095

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

Inactive Ingredients

<u> </u>	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 903K93S3TK)	

Packaging

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l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
п				

1 NDC:53113-095-08 236.5 mL in 1 BOTTLE; Type 0: Not a Combination Product 07/27/2020

Marketing Information

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	07/27/2020		

Labeler - GADAL Laboratories, Inc (841305639)

Establishment Name Address ID/FEI Business Operations GADAL Laboratories, Inc 841305639 manufacture(53113-095)

Revised: 7/2020 GADAL Laboratories, Inc