HAND SANITIZER- ethyl alcohol gel Biolab International Incorporated

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 62%

Purpose

Antiseptic

Uses hand sanitizer to help reduce bacteria on the skin. For occassional and personal domestic use

Warnings

for external use only: hands

Flammable. Keep away from fire or flame

when using this product, avoid contact with eyes, in case of contact, rinse eyes thoroughly with water, avoid contact with broken skin.

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

Keep out of reach of children. children under 6, use only under adult supervision, Not recommended for infants.

For external use only. Do not drink.

If swallowed, seek professional assistance or contact a poison control center.

Directions. Place enough product in your palm to thoroughly spread on both hands and rub into skin until dry.

Other information. do not store above 105°FI may discolor some fabics. harmful to wood finished and plastics

Inactive ingredients acrylates/C10-C30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, glycerin, maltodextrin, propylene glycol, water, triethanolamine, Fragrance. FD&C Red No.4

Drug Facts

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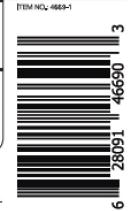
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PURE PASSION ™



HAND SANITIZER

ethyl alcohol gel

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NDC:72264-028 HUMAN OTC DRUG Item Code (Source) Product Type

TOPICAL **Route of Administration**

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name

Strength

TROLAMINE (UNII: 9O3K93S3TK)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:72264-028- 01	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/29/2020		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/29/2020	

Labeler - Biolab International Incorporated (200167919)

Revised: 6/2020 Biolab International Incorporated