

ANTI-BACTERIAL HAND GEL - ethyl alcohol gel
UniGroup Wholesale 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 Ingredients
Ethyl Alcohol 62%

Purpose

Antiseptic

Use: To help reduce bacteria on the skin

Warnings: For external use only.

Flammable. Keep away from fire or flame.

Stop use and ask a doctor if irritation or rash appears and lasts.

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

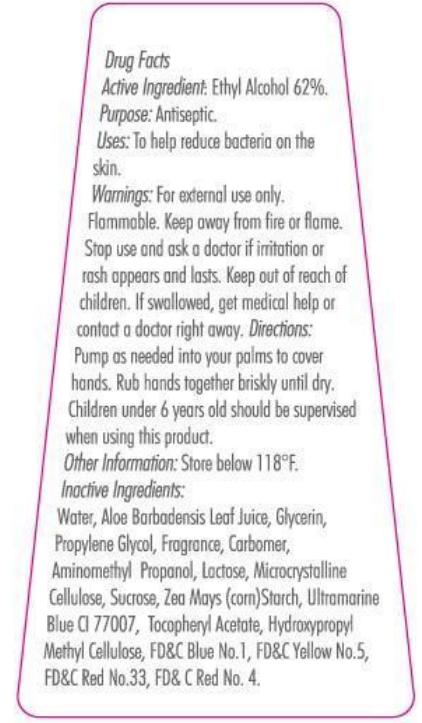
Directions:

Pump as needed into your palms to cover hands. Rub hands together briskly until dry. Children under 6 years old should be supervised when using this product.

Other Information:

Store below 118 F

Inactive Ingredients:Water, Aloe Barbadensis Leaf Juice, Glycerin, Propylene Glycol, Fragrance, Carbomer, Aminomethyl Propanol, Lactose, Microcrystalline Cellulose, Sucrose, Zea Mays (corn) Starch, Ultramarine Blue CI 77007, Tocopheryl Acetate, Hydroxypropyl Methyl Cellulose, FD&C Blue No.1, FD&C Yellow No.5, FD&C Red No.33, FD&C Red No.4.



ANTI-BACTERIAL HAND GEL			
ethyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69358-0005
Route of Administration	TOPICAL		
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
WATER (UNII: 059QF0K00R)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)			
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
LACTOSE (UNII: J2B2A4N98G)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
SUCROSE (UNII: C151H8M554)			
STARCH, CORN (UNII: O8232NY3SJ)			
ULTRAMARINE BLUE (UNII: I39WR998B1)			
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			

HYPROMELLOSES (UNII: 3NXW29V3WO)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69358-0005-1	29 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/12/2014	

Labeler - UniGroup Wholesale Inc. (079591424)

Revised: 11/2014

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