## ANTI-BACTERIAL HAND GEL- ethyl alcohol gel UniGroup Wholes ale 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.

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## **Active Ingredient:**

Ethyl Alcohol 62%

**Purpose** Antiseptic

*Warnings:* For external use only.

Flammable. Keep away from fire or flame.

Stop use and ask for 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.

*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, Hydroxpropyl Methyl Cellulose, FD&C Blue No.1, FD&C Yellow No.5, FD&C Red No.33, FD&C Red No.4.

Other Information: Store below 118 F.

*Use*To help reduce bacteria on the skin





Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69358-0018	
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: 059QF0KO0R)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)		
ULTRAMARINE BLUE (UNII: 139 WR998BI)		
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)		
LACTOSE (UNII: J2B2A4N98G)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
SUCROSE (UNII: C151H8 M554)		
STARCH, CORN (UNII: O8232NY3SJ)		
ALPHA-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)		
HYPROMELLOSES (UNII: 3NXW29 V3WO)		
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: X3W0 AM1JLX)		

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:69358-0018-	29 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/24/2016	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	03/24/2016		

## Labeler - UniGroup Wholesale Inc. (079591424)

Revised: 3/2016 UniGroup Wholesale Inc.