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.

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





Active Ingredient: Ethyl Alcohol 62%. Purpose: Antiseptic. Uses: To help reduce bacteria on the 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 Cl 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:69358-0017
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: PDC6 A3C0 OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)		
ULTRAMARINE BLUE (UNII: I39 WR9 9 8 BI)		
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: 9E8 X80 D2L0)		
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: X3W0 AM1JLX)		

Packaging	ıckaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:69358-0017-	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.