

**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.*

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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 Barbadosensis 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.

**Other Information:** Store below 118 F.

**Use**To help reduce bacteria on the skin



**ANTI-BACTERIAL HAND GEL**

ethyl alcohol gel

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:69358-0016

**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: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
ULTRAMARINE BLUE (UNII: I39WR998BI)	
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	
LACTOSE (UNII: J2B2A4N98G)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SUCROSE (UNII: C151H8M554)	
STARCH, CORN (UNII: O8232NY3SJ)	
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:69358-0016-1	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)