

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 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.

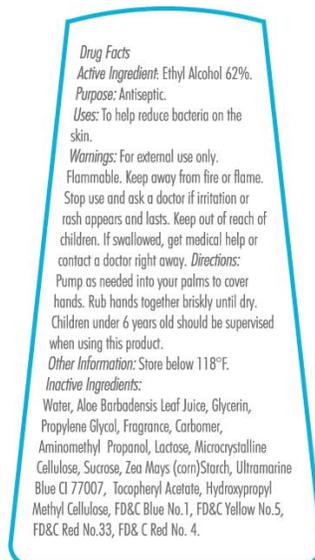
Directions:

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.

UseTo help reduce bacteria on the skin



ANTI-BACTERIAL HAND GEL
 ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69358-0020

Route of Administration	TOPICAL
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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:69358-0020-1	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)