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





Drug Facts 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:69358-0002

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthAlcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M)Alcohol62 mL in 100 mL

Inactive Ingredients

Ingredient Name Strength
WATER (UNII: 059QF0KO0R)

GLYCERIN (UNII: PDC6A3C0OX)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)

AMINO METHYLPRO PANOL (UNII: LU49 E 6626Q)

ALOE VERA LEAF (UNII: ZY81Z83H0X)

LACTOSE (UNII: J2B2A4N98G)

CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)

SUCROSE (UNII: C151H8M554)

STARCH, CORN (UNII: O8232NY3SJ)

ULTRAMARINE BLUE (UNII: I39WR998BI)

.ALPHA.-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)

FD&C BLUE NO. 1 (UNII: H3R47K3TBD) FD&C YELLOW NO. 5 (UNII: I753WB2F1M) D&C RED NO. 33 (UNII: 9DBA0SBB0L) ED&C RED NO. 4 (UNII: Y3W0AM(H Y))	HYPROMELLOSES (UNII: 3NXW29V3WO)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
EDOC DED NO. A (UNIII, VONO AMILI V)	D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 4 (UNII: ASWUAMIJLA)	FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69358-0002-1	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 UniGroup Wholesale Inc.