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 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 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 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 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

ANTI-BACTERIAL HAND GEL

ethyl alcohol gel

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:69358-0003

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ULTRAMARINE BLUE (UNII: I39WR998BI)

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

Ingredient Name

Basis of Strength
Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M)

Alcohol (UNII: 3K9958V90M) Alcohol 62 mL in 100 mL

Inactive Ingredients

Ingredient Name

WATER (UNII: 059QF0KO0R)

GLYCERIN (UNII: PDC6A3C0OX)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

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

AMINOMETHYLPROPANOL (UNII: LU49E6626Q)

ALOE VERA LEAF (UNII: ZY81Z83H0X)

LACTOSE (UNII: J2B2A4N98G)

CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)

SUCROSE (UNII: C151H8M554)

STARCH, CORN (UNII: O8232NY3SJ)

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			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:69358-0003-1	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.