

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.

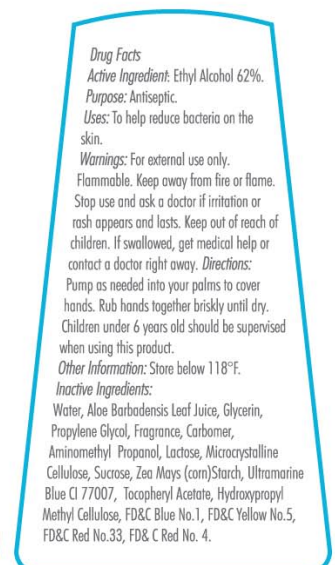
Directions:

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:69358-0019 | |
| 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:69358-0019-1 | 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)