

ANTI-BACTERIAL HAND GEL- ethyl alcohol gel

Jean Pierre 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. Do not apply around eyes. Do not use in ears or mouth. When using this product, avoid contact with eyes. In case of contact, flush eyes with water.

Stop use or ask for a doctor if redness or irritation develops and persists for more than 72 hours.

Keep out of reach of children. Children must be supervised in use of this product.

Directions: Squeeze as needed into your palms and thoroughly spread on bottom hands. Rub into skin until dry.

Inactive ingredients: Water, Aloe Barbadensis Leaf, Glycerin, Propylene Glycol, Carbomer, Triethanolamine, Fragrance, FD&C Red No.4, FD&C Blue No.1, FD&C Yellow No.5

Uses: Hand sanitizer to help decrease bacteria on the skin when water, soap & towel are not available. Recommended for repeated use

Other information

Do not store in temperature over 118 F.



ANTI-BACTERIAL HAND GEL

ethyl alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70483-001 |
| 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) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| FD&C RED NO. 4 (UNII: X3W0AM1JLX) | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70483-001-01 | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/25/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 05/25/2016 | |

Labeler - Jean Pierre Inc. (138328393)

Revised: 5/2016

Jean Pierre Inc.