

INSTANT HAND SANITIZER- ethyl alcohol gel
BB17, LLC

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:

Antimicrobial

WARNING:

FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME. FOR EXTERNAL USE ONLY. DO NOT USE IN THE EYES.

DISCONTINUE USE IF IRRITATION AND REDNESS DEVELOP. IF CONDITION PERSISTS FOR MORE THAN 72 HOURS, CONSULT A DOCTOR OR PHYSICIAN.

KEEP OUT OF REACH OF CHILDREN.

Directions:

Rub into hands until dry.

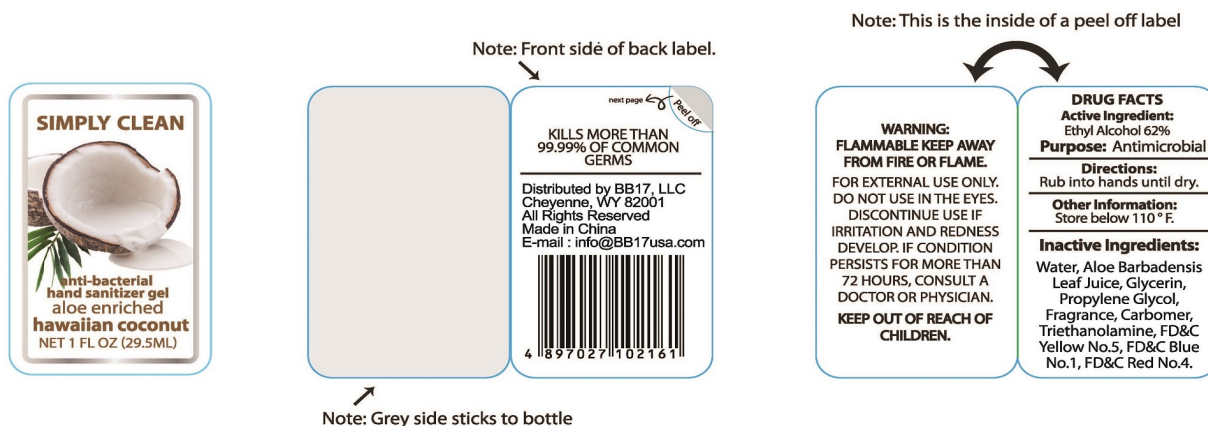
Inactive Ingredients:

Water, Aloe barbadensis Leaf Juice, Glycerin, Propylene Glycol, Fragrance, Carbomer, Triethanolamine, FD&C Yellow NO.5, FD&C Blue NO.1, FD&C Red NO.4.

Other Information:

Store below 110 F.

KILLS MORE THAN 99.99% OF COMMON GERMS



INSTANT HAND SANITIZER

ethyl alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53603-1034 |
| 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 BLUE NO. 1 (UNII: HBR47K3TBD) | |
| FD&C RED NO. 4 (UNII: X3W0AM1JLX) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:53603-1034-1 | 29.5 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 09/26/2015 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph not final | part333E | 09/26/2015 | |

Labeler - BB17, LLC (828378294)

Revised: 11/2015

BB17, LLC