

GINGERBREAD- antibacterial hand sanitizer gel
Brands International

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.

Gingerbread

GINGERBREAD ANTIBACTERIAL HAND SANITIZER

ACTIVE INGREDIENT: ETHYL ALCOHOL 62% PURPOSE ANTISEPTIC

ANTISEPTIC

USES: TO DECREASE BACTERIA ON THE SKIN AND CLEAN HANDS. RECOMMENDED FOR REPEATED USE

WARNING: FOR EXTERNAL USE ONLY. FLAMMABLE, KEEP AWAY FROM FIRE OR FLAME.

DO NOT GET INTO EYES. IF CONTACT OCCURS, RINSE THOROUGHLY WITH WATER.

DISCONTINUE USE IF IRRITATION OR REDNESS DEVELOP. IF IRRITATION PERSISTS FOR MORE THEN 72 HOURS, CONSULT A DOCTOR.

SUPERVISE CHILDREN IN THE USE OF THIS PRODUCT.

OTHER INFORMATION MAY DISCOLOR CERTAIN FEBRICS OR SURFACES.

INACTIVE INGREDIENTS: WATER, ISOPROPYL ALCOHOL, GLYCERIN, CARBOMER, AMINOMETHYL PROPANOL, FRAGRANCE, PROPYLENE GLYCOL, ISOPROPYL MYRISTATE, ALOE BARBADENSIS LEAF JUICE, TOCOPHEROL ACETATE (VITAMIN E), SUNFLOWER (HELIANTHUS ANNUUS) SEED EXTRACT, RED 40 (CI 16035), Yellow 5 (CI 19140), Blue 1 (CI 42090)

GINGERBREAD ANTIBACTERIAL HAND SANITIZER

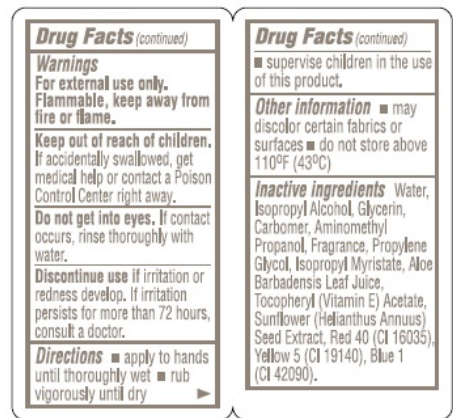


BACK
ADHESIVE SIDE



BACK LABEL

BACK LABEL INSIDE



GINGERBREAD

antibacterial hand sanitizer gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50 157-103 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-------------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 620 mL in 1000 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| WATER (UNII: 059QF0KO0R) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) | |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-------------------|--|----------------------|--------------------|
| 1 | NDC:50 157-103-01 | 29 mL in 1 BOTTLE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.) | 10/01/2015 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final | part333A | 10/01/2015 | |

Labeler - Brands International (243748238)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|----------------------|----------------|---------------|----------------------------|
| Brands International | | 243748238 | manufacture(50 157-103) |