

FROSTED SUGAR COOKIE- 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.

FROSTED SUGAR COOKIE 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 INFORMATIONMAY DISCOLOR CERTAIN FEBRICS OR SURFACES.

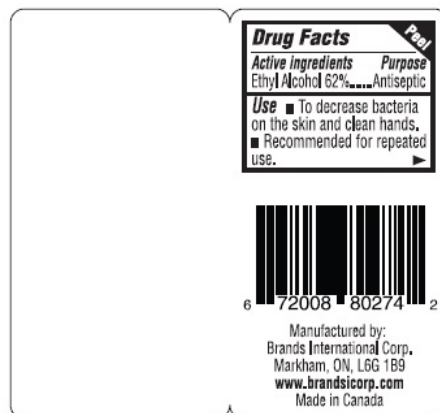
INACTIVE INGREDIENTS: WATER, PISOPROPYL ALCOHOL, GLYCERIN, CARBOMER, AMINOMETHYL PROPANOL, PROPYLENE GLYCOL, ISOPROPYL MYRISTATE, ALOE BARBADENSIS LEAF JUICE, TOCOPHEROL ACETATE, SUNFLOWER (HELIANTHUS ANNUUS) SEED EXTRACT, MAY CONTAIN: FD&C BLUE NO. 1(CI 42090), FD&C RED NO. 40(CI 16035), FD&C YELLOW NO. 5 (CI 19140)

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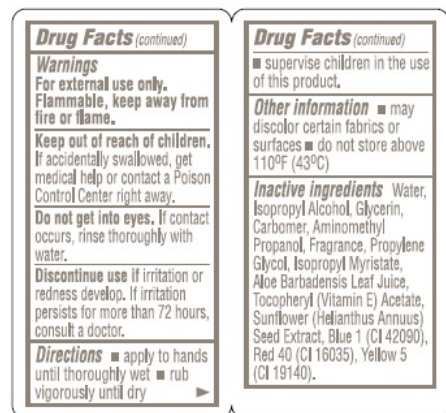


BACK
ADHESIVE SIDE

BACK LABEL



BACK LABEL INSIDE



FROSTED SUGAR COOKIE
 antibacterial hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50 157-104
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:50 157-104-01	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(50 157-104)