SUGAR PLUM- 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.

SUGAR PLUM 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 THROUGHLY 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.

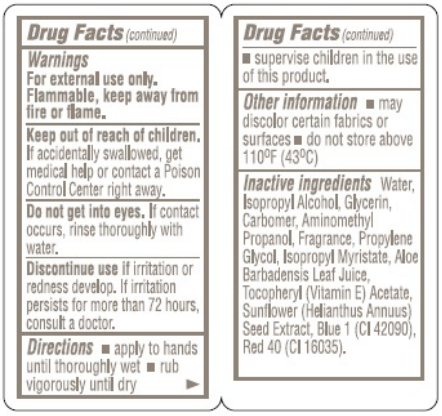
INACTIVE INGREDIENTS: WATER, PISOPROPYL ALCOHOL, GLYCERIN, CARBOMER, AMINOMETHYL PROPANOL, PROPYLENE GLYCOL, ISOPROPYL MYRISTATE, ALOE BARBADENSIS LEAF JUICE, TOCOPHEROL ACETATE, SUNFLOWER (HELIANTHUS ANNUUS) SEED EXTRACT, MAY CONTAIN: FD&C BLUE NO. 1(CI 42090), FD&C RED NO. 40(CI 16035), FD&C YELLOW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

SUGAR PLUM ANTIBACTERIAL HAND SANITIZER

BACK
ADHESIVE SIDE

BACK LABEL

BACK LABEL INSIDE



SUGAR PLUM
antibacterial hand sanitizer gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50157-109
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 HOMOPOLYMER 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: H3R47K3TBD)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50157-109-01	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(50157-109)