

ISLAND COTTON- antibacterial hand sanitizer gel
Brands International Corp

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

Use

To decrease bacteria on the skin and clean hands

Recommended for repeated use

Warnings

For external use only

Flammable, keep away from fire or flame

Keep out of reach of children

If accidentally swallowed, get medical help or contact a Poison Control Center right away

Do not get into eyes

If contact occurs, rinse thoroughly with water

Discontinue use if irritation or redness develop. If irritation persists for more than 72 hours, consult a doctor

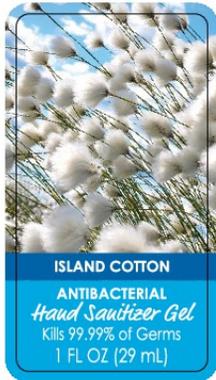
Directions

- apply to hands until thoroughly wet
- rub vigorously until dry
- supervise children in the use of this product

Other Information

- May discolour certain fabrics or surfaces
- do not store above 110 F (43 C)

Inactive Ingredients - Water, Isopropyl Alcohol, Glycerin, Carbomer, Aminomethyl Propanol, Fragrance, Propylene Glycol, Isopropyl Myristate, Aloe Barbadensis Leaf Juice, Tocopheryl (Vitamin E) Acetate, Sunflower (Helianthus Annulus) seed extract, Blue 1 (Cl 42090)



BACK
ADHESIVE SIDE

BACK LABEL

BACK LABEL INSIDE



ISLAND COTTON

antibacterial hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50 157-117
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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
SUNFLOWER SEED (UNII: R9N3379M4Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50 157-117-01	29 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/02/2015	

Labeler - Brands International Corp (243748238)

Establishment			
Name	Address	ID/FEI	Business Operations
Brands International Corp		243748238	manufacture(50157-117)

Revised: 11/2015

Brands International Corp