

PRISTINE1- alcohol gel
Caribbean Spirit Imports 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(s)

Alcohol 70% v/v. Purpose: Antimicrobial

Drug Facts

Active Ingredient

Purpose

Ethyl Alcohol 70% v/v Antimicrobial

Use: Hand sanitizer to help reduce bacteria on skin.

Warnings: Flammable. Keep away from fire or flame.
For external use only.

When using this product do not use in or near the eyes.
In case of contact, flush thoroughly with water. Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

DIRECTIONS: Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using.

Other Information: STORE BELOW 110F. May discolor some fabrics and surfaces.

INACTIVE INGREDIENTS: Water, Triethanolamine, Carbomer, Aloe Vera Extract, Phenoxyethanol

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Package Label - Principal Display Panel

Hand Sanitizer Gel with Aloe Vera

Kills 99.9% of Germs



PRISTINE1

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77605-110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	0.055 mL in 1 mL
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.002 mL in 1 mL
WATER (UNII: 059QF0K00R)	0.45 mL in 1 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.006 mL in 1 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.001 mL in 1 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77605-110-01	325 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77605-110-02	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/25/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Caribbean Spirit Imports LLC (044842772)