COCONUT ANTI BACTERIAL HAND SANITIZER- alcohol gel B2 Fashions Inc.

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.

Coconut Anti-Bacterial Hand Sanitizer

Drug Facts

Active ingredients

Ethyl Alcohol 62%

Purpose

Antiseptic

Uses

- hand sanitizer to help decrease bacteria on the skin.
- When water, soap & towel are not available.
- recommended for repeated use

Warnings

For external use only.

Flammable. Keep away from fire or flame.

Do not apply around eyes.

Do not use

in ears & mouth

When using this product,

avoid contact with eyes. In case of contact flush eyes with water.

Stop use and ask a doctor if

redness or irritation develop and persist for more than 72 hours.

Keep out of reach of children.

Children must be supervised in use of this product.

Directions

- pump as needed into your palms and thoroughly spread on both hands.
- rub into skin until dry.

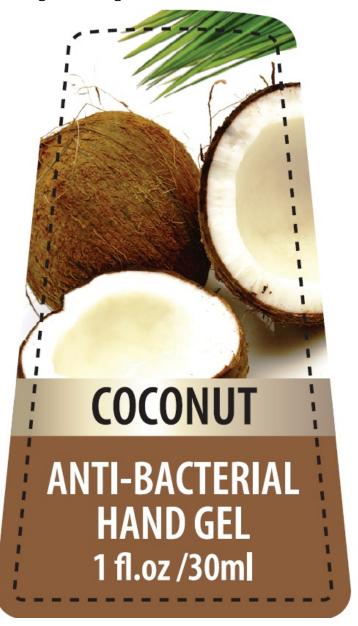
Other information

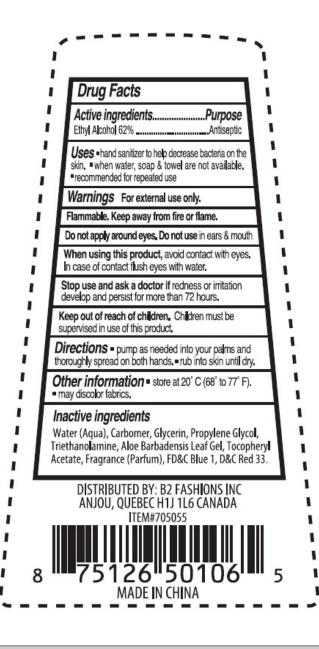
- store at 20° C (68° to 77° F).
- may discolor fabrics.

Inactive ingredients

Water (Aqua), Carbomer, Glycerin, Propylene Glycol, Triethanolamine, Aloe Barbadensis Leaf Gel, Tocopheryl Acetate, Fragrance (Parfum), FD&C Blue 1, D&C Red 33.

Package Labeling:





COCONUT ANTI BACTERIAL HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71372-001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	620 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
CARBO XYPO LYMETHYLENE (UNII: 0 A5MM307FC)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
TROLAMINE (UNII: 9O3K93S3TK)		
.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
D&C RED NO.33 (UNII: 9DBA0SBB0L)		

	Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:71372-001-30	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2017		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	04/05/2017		

Labeler - B2 Fashions Inc. (243904310)

Revised: 4/2017 B2 Fashions Inc.