BOTANIKA AUSTRALIA ALOE VERA ANTI BACTERIAL HAND SANITIZER- alcohol gel COGNESCENTI PTY. LTD.

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.

hand sanitizer

Drug Facts

Active ingredient

SD Alcohol 40-B 75% v/v

Purpose

Antiseptic

USE

• hand sanitizer to help reduce bacteria on the skin.

Warnings

For external use only.

Flammable. Keep away from fire and flame.

When using this product

avoid contact with eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if

• irritation and redness develops.

Keep out of reach of children.

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

Directions

- Put enough on you palm to cover hands. Rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product.

Other information:

- Store at 200 to 250 (680 to 770).
- May discolor some fabrics or surface.

Inactive ingredients

Purified Water (Aqua), Cross Polymer, Triethanolamine, Parfum (Fragrance), Citronellol, Linalool, Lilial, Benzyl Salicylate, Hexyl Cinnamic Aldehyde, Ceranil, Cumarin, Hydroxycitronellal, Amyl Cinnamic Aldehyde, Eugenol Cinnamyl Alcohol, Eugenol Cinnamyl Alcohol, Methyl Ionone, Benzyl Benzoate, Benzyl Alcohol, Citral, Iso Eugenol, Limonene

package



BOTANIKA AUSTRALIA ALOE VERA ANTI BACTERIAL HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79978-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
water (UNII: 059QF0KO0R)		
TROLAMINE (UNII: 9O3K93S3TK)		
BENZYL SALICYLATE (UNII: WAO5MNK9TU)		
.ALPHAHEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)		
BENZYL BENZOATE (UNII: N863NB338G)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
CITRAL (UNII: T7EU0O9VPP)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79978-009-01	$500\ mL$ in $1\ BOTTLE;$ Type 0: Not a Combination Product	08/28/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/28/2020	

Labeler - COGNESCENTIPTY. LTD. (745278551)

Establishment				
Name	Address	ID/FEI	Business Operations	
COGNESCENTI PTY. LTD.		745278551	manufacture(79978-009)	

Revised: 8/2020 COGNESCENTI PTY. LTD.