DISPOSABLE DISINFECTANT GEL- alcohol gel Zhengzhou Airport Kangyue Biotechnology Co., 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.

Disposable Disinfectant Gel

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Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Disposable Disinfectant Gel

Use

Disposable Disinfectant Gel to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)
WATER
"ALPHA.-TOCOPHEROL ACETATE, DL"
GLYCERIN
TROLAMINE
ALOE

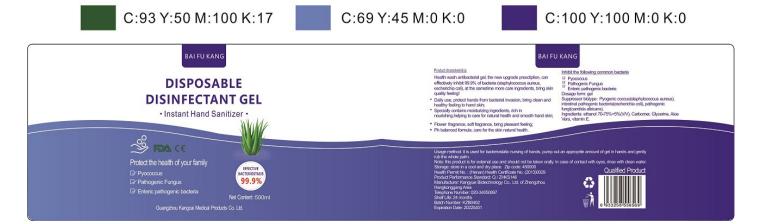
Package Label - Principal Display Panel

165*78mm





220*55mm





Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0KO0R)	
.ALPHATO COPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
TROLAMINE (UNII: 903K93S3TK)	
ALOE (UNII: V5VD430 YW9)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:78051-101-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			
2	NDC:78051-101-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			
3	NDC:78051-101-03	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			
4	NDC:78051-101-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			
5	NDC:78051-101-05	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			

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

Labeler - Zhengzhou Airport Kangyue Biotechnology Co., Ltd. (409875170)

Establishment				
Name	Address	ID/FEI	Business Operations	
Zhengzhou Airport Kangyue Biotechnology Co., Ltd.		409875170	manufacture (78051-101)	

Revised: 5/2020 Zhengzhou Airport Kangyue Biotechnology Co., Ltd.