ALV71 PURE SANITIZER 100ML- alcohol gel MIKOLAB 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.

Active Ingredient(s)

Alcohol 70%

Purpose

Purpose: Antiseptic

Use

Hand sanitizing to help reduce bacteria on the skin

Warnings

- □ For external use only.
- ☐ Flammable, keep away from fire or flame.
- $\ \square$ When using this product, avoid contact with the eyes. In case of contact, rinse eyes thoroughly with water.
- □ Stop use and ask a doctor if irritation or redness appears and lasts.
- ☐ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

I Take suitable amount of sanitizer in the hand. Wet thoroughly and rub hands together until dry

Other information

☐ Store in room temperature 0~30☐

Inactive ingredients

U Water (Aqua), Carbomer, Triethanolamine, Polysorbate 20, Camellia Sinensis Leaf Extract, Glycerin, Tocopheryl Acetate, Fragrance (Parfum)

Package Label - Principal Display Panel



ALV71 PURE SANITIZER 100ML

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76886-002
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

	Ingredient Name	Basis of Strength	Strength
ı	alcohol (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	alcohol	70 mL in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
Water (UNII: 059QF0KO0R)				
Polysorbate 20 (UNII: 7T1F30V5YH)				
Glycerin (UNII: PDC6A3C0OX)				

ı	Pa	ckaging			
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 N	NDC:76886-002-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/29/2020		

Labeler - MIKOLAB CO .LTD (695791492)

Establishment			
Name	Address	ID/FEI	Business Operations
MIKOLAB CO .LTD		695791492	label(76886-002)

Establishment				
Name	Address	ID/FEI	Business Operations	
HEALKINBIO CO.		694039685	manufacture(76886-002)	

Revised: 4/2020 MIKOLAB CO .LTD