HAND SANITIZER- alcohol gel Innovative Tool and design

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)

Ethyl Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer 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

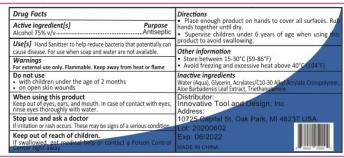
Water (Aqua), Glycerin, Acrylates/c10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadnsis Leaf Extract, Triethanolamine

Package Label - Principal Display panel

474 ml NDC: 78900-624-10









HAND SANITIZER

alcohol gel

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:78900-631

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			
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL			
WATER (UNII: 059QF0KO0R)				

Product Characteristics				
Color		Score		
Shape	SEMI-CIRCLE	Size		
Flavor		Imprint Code		
Contains				

	Packaging				
4	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
:	NDC:78900- 631-10	474 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/26/2020		
2	NDC:78900- 631-11	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/26/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	10/26/2020		

Labeler - Innovative Tool and design (011289563)

Registrant - Innovative Tool and design (011289563)

Establishment			
Name	Address	ID/FEI	Business Operations

Innovative Tool and design	011289563	relabel(78900-631)	
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Establishment			
Name	Address	ID/FEI	Business Operations
Ningbo Meiteli Cosmetic co.		546624772	manufacture(78900-631)

Revised: 2/2021 Innovative Tool and design