WASH FREE DISINFECTION GEL- alcohol gel Guangzhou Ruihe Medical Technology 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 75% v/v

Purpose

Antiseptic

Use

Hand sanitizing for intact skin

Warnings

- External use, keep out of reach of children, avoid eyes and ear.
- Use with caution for who allergic to ethanol.
- Keep away from light, sealed, moisture-prood, store in a cool, dry place.
- Flammable. Keep away from fire or flame

Do not use

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

Pruritus, redness, and swelling of hands, allergy, etc.

Keep out of reach of children.

Directions

- Wet hand with proper amount of the product, and keep the liquid for 1 minute until the liquid covers the whole hand and dry.
- Children under 6 years of age when using this product to avoid swallowing.

Other information

- Do not store above 40C. May discolor some fabrics and surfaces.
- Store between 15-30C

Inactive ingredients

Water, Triethanolamine, Carbomer

Package Label - Principal Display Panel







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Manufacturer: Guangzhou Ruihe Medical Technology Co.,Ltd. LOT NO.: RH2020001 Made in China









10.14 fl oz (300ml)



Drug facts

Uses:

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WASH FREE DISINFECTION GEL

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Coo	le (Source) NDC:74180-001	
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

mactive ingredients		
Ingredient Name	Strength	
TROLAMINE (UNII: 9O3K93S3TK)		
CARBO MER HO MO PO LYMER, UNSPECIFIED TYPE (UNII: 0 A5MM30 7FC)		

WATER (UNII: 059QF0KO0R)

Packaging

	8 8	8 8			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:74180-001- 01	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020		
2	NDC:74180-001- 02	100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020		
3	NDC:74180-001- 03	300 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020		
4	NDC:74180-001- 04	500 mL in 1 BOTTLE, PUMP; 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 - Guangzhou Ruihe Medical Technology Co.,Ltd. (419114912)

Establishment

Establishment				
	Name	Address	ID/FEI	Business Operations
	Guangzhou Ruihe Medical Technology Co.,Ltd.		419 1149 12	manufacture (74180-001)