ALCOHOL DISINFECTANT- alcohol gel Qingdao Maixing 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.

Hand Sanitizer

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (75%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 75% v/v. Purpose:disinfection and sterilization

Purpose

Antiseptic, Hand Sanitizer.

disinfection and sterilization

Use

helps decrease bacteria on skin.recommended for repeated use.

Warnings

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

Do not use

- do not use on children under 6 years old.
- do not use on open skin wounds.
- keep out of eyes.in case of contact with eyes, flush thoroughly with water
- avoid contact with broken skin
- do not inhale or ingest

irritation and redness develop condition persists for more tahn 72 hours

if swallowed, get medical help or contact a poison control center right away

Directions

wet hands thoroughly with product and allow to dry without wiping. this product is not a substitute for drugs or medical devices. keep container tightly closed and store in a well cool ventilated.

Other information

- do not store above 105.F
- may discolor some fabrics
- harmful to wood finisher and plastics

Inactive ingredients

water,carbomer940,trolamine

Package Label - Principal Display Panel

300 mL NDC:



ALCOHOL DISINFECTANT

alcohol gel

HUMAN OTC DRUG	Item Code (Source)	NDC:75711-002
TOPICAL		

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	225 mL in 300 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
CARBOMER 940 (UNII: 4Q93RCW27E)	1.05 mL in 300 mL		
TROLAMINE (UNII: 903K93S3TK)	0.6 mL in 300 mL		

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:75711-002-0	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/22/2020	

Labeler - Qingdao Maixing Biotechnology Co.,Ltd (417832907)

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