ALCOHOL DISINFECTANT- alcohol liquid 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 antiseptic

Purpose

Antiseptic, Hand Sanitizer

purpose: disinfection and antiseptic

Use

Suitable for sterilization and disinfection of the surface of the object and the complete skin of the human body.

Warnings

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

Do not use

- do not use on children 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.

stop use and ask a doctor if irritation and redness develop, condition persists for more tahn 72 hours Keep out of reach of children. If swallowed, get medical help or contact a poison control center right

Directions

this product is for extermal use.apply this product to skin, hands and general objects this product is not a substitute for drugs or medical devices use with caution; infants, pregnant women and breastfeeding women keep out of reach of children, do not use on children 6 years old.do not use on open skin wounds

Other information

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

Inactive ingredients

water

Package Label - Principal Display Panel

50 mL NDC:



ALCOHOL DISINFECTANT alcohol liquid Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:75711-003 Route of Administration TOPICAL

| Active Ingredient/Active Moiety | | | | | |
|--|-------------------|------------------|--|--|--|
| Ingredient Name | Basis of Strength | Strength | | | |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 37.5 mL in 50 mL | | | |

| Inactive Ingredients | | | | | |
|--------------------------|----------|--|--|--|--|
| Ingredient Name | Strength | | | | |
| WATER (UNII: 059QF0KO0R) | | | | | |

| ı | Packaging | | | | | | |
|---|-----------|--------------|--|-----------------------------|---------------------------|--|--|
| ı | # It | em Code | Package Description | Marketing Start Date | Marketing End Date | | |
| ı | 1 NDC | 75711-003-01 | 50 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 | | | | |
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Labeler - Qingdao Maixing Biotechnology Co.,Ltd (417832907)

Revised: 4/2020 Qingdao Maixing Biotechnology Co.,Ltd