KWORK ETHANOL DISINFECTION GEL- alcohol gel Zhejiang Quark 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.

Active Ingredient(s)

Alcohol 75% w/w. 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

Carbomer, Triethanciamine, Essence, purified water USP

Package Label - Principal Display Panel

60 mL NDC: 78867-002-01

消毒凝胶 尺寸:100*70mm



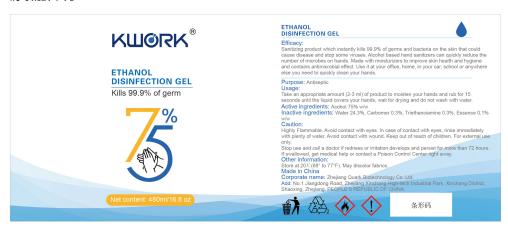
100 mL NDC: 78867-002-02

消毒凝胶 尺寸:110*73mm



480mL NDC: 78867-002-03

消毒凝胶 尺寸: 206*87mm



KWORK ETHANOL DISINFECTION GEL

alcohol gel

| Product Information | | | | | |
|-------------------------|----------------|--------------------|---------------|--|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78867-002 | | |
| 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 | | | |
| ACRYLIC ACID (UNII: J94PBK7X8S) | 0.3 mL in 100 mL | | | |
| TROLAMINE (UNII: 903K93S3TK) | 0.3 mL in 100 mL | | | |
| WATER (UNII: 059QF0KO0R) | | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
|-----------------------|----------------------|---|-----------------------------|---------------------------|--|
| 1 | NDC:78867-002-01 | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | | |
| 2 | NDC:78867-002-02 | $100\ mL$ in $1\ BOTTLE;$ Type $0\colon Nota$ Combination Product | 03/30/2020 | | |
| 3 | NDC:78867-002-03 | 480 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | | |
| | | | | | |
| Marketing Information | | | | | |
| | Marketing Categor | y Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| O | TC monograph not fir | al part333A | 03/30/2020 | | |

Labeler - Zhejiang Quark Biotechnology Co., Ltd. (547091082)

| Establishment | | | | | |
|--|---------|-----------|------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| Zhejiang Quark Biotechnology Co., Ltd. | | 547091082 | manufacture(78867-002) | | |

Revised: 6/2020 Zhejiang Quark Biotechnology Co., Ltd.