

HAND SANITIZER- alcohol liquid
ALAMEDA WHOLESALE AND LIQUIDATORS INC.

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

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.

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.

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, glycerin, squalane, panthenol, inulin, sodium hyaluronate, fructose, tocopherol acetate, acrylates/C-10-30 Alkyl Acrylate Crosspolymer, aminomethyl propanol

Package Label - Principal Display Panel

3800 mL NDC: 80179-001-01



HAND SANITIZER

alcohol liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:80179-001 |
| 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 |
|---|----------|
| CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO) | |
| FRUCTOSE, DL- (UNII: 02T79V874P) | |
| .ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| WATER (UNII: 059QF0KO0R) | |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | |
| PANTHENOL (UNII: WV9CM0O67Z) | |

INULIN (UNII: JOS53KRJ01)

HYALURONATE SODIUM (UNII: YSE9PPT4TH)

SQUALANE (UNII: GW89575KF9)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:80179-001-01 | 3800 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 - ALAMEDA WHOLESAL E AND LIQUIDATORS INC. (017670348)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------------|---------|-----------|------------------------|
| Zhejiang iColor Biotech Co., Ltd. | | 554528308 | manufacture(80179-001) |

Revised: 8/2020

ALAMEDA WHOLESAL E AND LIQUIDATORS INC.