**HAND SANITIZER- ethyl alcohol liquid**
**Barley Creek Associates, L.P.**

*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.*

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Store between 15-30C (59-86F)
Avoid freezing and excessive heat above 40C (104F)

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.

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 me signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Purpose - Antiseptic

Use(s) Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Active ingredient(s) - Alcohol 80% v/v

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## DRUG FACTS LABEL

***Drug Facts***

***Active ingredient[s]*** ***Purpose***

Alcohol 80% v/v..... Antiseptic

***Use[s]***

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***Warnings***

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***Other information***

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## PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):

**Alcohol Antiseptic 80%**
**Topical Solution**

**Hand Sanitizer**
**Non-sterile Solution**

**[Insert Volume of Product in mL]**

## HAND SANITIZER
ethyl alcohol liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:73995-100 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ALCOHOL** (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 80 mL in 100 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **HYDROGEN PEROXIDE** (UNII: BBX060AN9V) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | NDC:73995-100-02 | 118.29 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/25/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333A | 03/25/2020 | |

## Labeler - Barley Creek Associates, L.P. (839325347)

## Registrant - Barley Creek Associates, L.P. (839325347)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Barley Creek Associates, L.P. | | 839325347 | manufacture(73995-100) |

Revised: 3/2020 Barley Creek Associates, L.P.