

HAND SANITIZER- isopropyl 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.

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Dosage & Administration section

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.

Warning Section

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.

Indications and Usage section

Purpose – Antiseptic Handsanitizer

Active Ingredient(s): Isopropyl Alcohol 75% v/v

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Purpose Section use

Use(s):

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Keep out of reach of Children

Keep out of Reach of children

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

SPL Unclassified Section

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:

Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.

Glycerol (1.45% v/v).

Hydrogen peroxide (0.125% v/v).

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.

Package Label Principal Display

Barley Creek 11:02

Hand Sanitizer

Active Ingredient(s): Isopropyl Alcohol 75% v/v

Non-sterile Solution

4 ounce – 118.29 ml

118 ml NDC: 73995-200-02

Package Label Display Panel - half gallon

Barley Creek 11:02

Hand Sanitizer

Active Ingredient(s): Isopropyl Alcohol 75% v/v

Non-sterile Solution

64 ounce – 1892.71 ml

118 ml NDC: 73995-200-03

HAND SANITIZER

isopropyl alcohol liquid

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	
Route of Administration		TOPICAL	NDC:73995-200	
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)			ISOPROPYL ALCOHOL	75 mL in 100 mL
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73995-200-02	118.3 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:73995-200-03	1892.71 mL in 1 BOTTLE, PLASTIC; 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 - 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(73995-200)