HAND SANITIZER- alcohol liquid Cane Creek Distillery

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 80% 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.

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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

glycerin, hydrogen peroxide, water

Package Label - Principal Display Panel

375 mL NDC: 77995-375-01



HAND SANITIZER

alcohol liquid

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77995-375	Product Information				
	G Item Code (Source) NDC:77995-375	HUMAN OTC DRUG	Product Type		
Route of Administration TOPICAL		TOPICAL	Route of Administration		

Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	300 mL in 375 mL

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6 A3C0 O X)				
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)				
WATER (UNII: 059QF0KO0R)				

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:77995-375- 01	375 mL in 1 BOTTLE, DISPENSING; 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 - Cane Creek Distillery (117524112)

Registrant - Cane Creek Distillery (117524112)

Establishment					
Name	Address	ID/FEI	Business Operations		
Cane Creek Distillery		117524112	manufacture(77995-375)		

Revised: 5/2020 Cane Creek Distillery