

## **CUT SPIKE HAND SANITIZER- alcohol liquid**

### **Cut Spike 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.*

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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:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. 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.

### **Active Ingredient(s)**



# HAND SANITIZER

Non-sterile Solution

Alcohol Antiseptic  
80% Topical Solution

1 Gallon (3785 ml)

MANUFACTURED BY: CUT SPIKE DISTILLERY LA VISTA, NE

## Drug Facts

### Active Ingredient[s]

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

### Purpose

### Use[s]

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.

### 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, purified water USP



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Antiseptic

Use



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**Package Label - Principal Display Panel**





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## CUT SPIKE HAND SANITIZER

alcohol liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76734-001
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)			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:76734-001-01	3776 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76734-001-02	207680 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
3	NDC:76734-001-03	1246080 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
4	NDC:76734-001-04	472 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:76734-001-05	236 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** - Cut Spike Distillery (122293847)

Establishment			
Name	Address	ID/FEI	Business Operations
Cut Spike Distillery		122293847	manufacture(76734-001)