

BIG SPRING SPIRITS HAND SANITIZER- big spring spirits hand sanitizer liquid
Nittany Valley Distilling, LLC

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.

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.

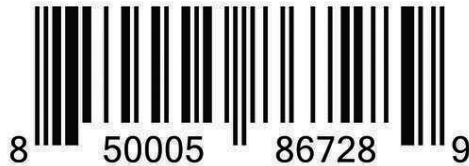
The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Drug Facts	
<i>Active ingredient[s]</i>	<i>Purpose</i>
Alcohol 80% v/v.....	Antiseptic
<i>Use[s]</i> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<i>Warnings</i> For external use only. Flammable. Keep away from heat or flame	
Do not use <ul style="list-style-type: none">• 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.	
<i>Directions</i> <ul style="list-style-type: none">• 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.	
<i>Other information</i> <ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F)	
<i>Inactive ingredients</i> glycerin, hydrogen peroxide, purified water	

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BIG SPRING SPIRITS
198 MATCH FACTORY PLACE
BELLEFONTE, PA 16823
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Purpose

Antiseptic, Hand Sanitizer

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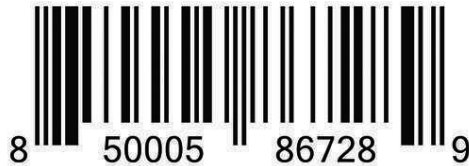
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Use

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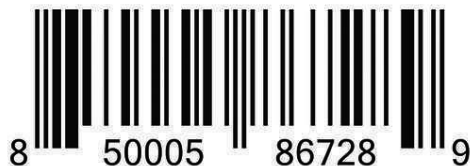
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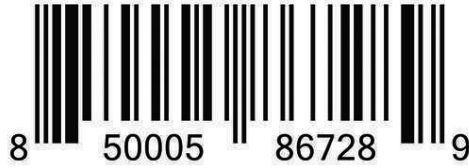


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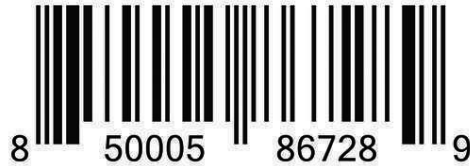


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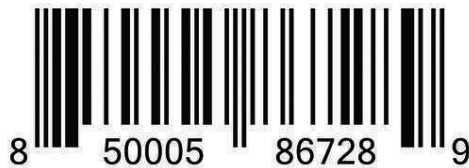
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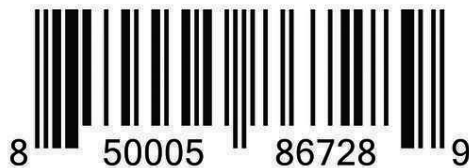
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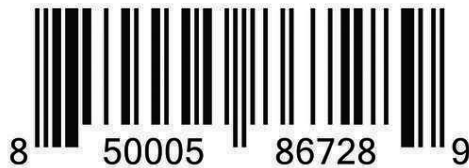
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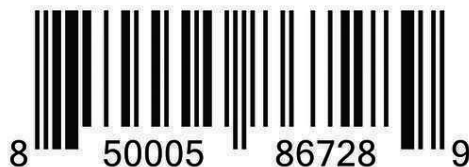
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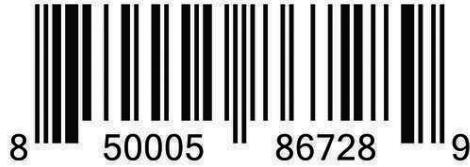


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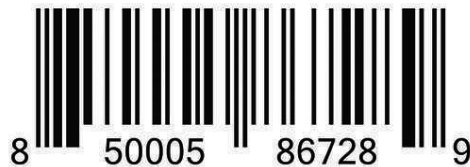
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Package Label - Principal Display Panel

237 mL NDC: 74358-001-1

BIG SPRING
: : : : SPIRITS : :

**ALCOHOL ANTISEPTIC &
TOPICAL SOLUTION**

WAND

HAND SANITIZI

NON-STERILE SOLUTION

LOT# 2020-001

BIG SPRING SPIRITS HAND SANITIZER

big spring spirits hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74358-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	189.6 mL in 237 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	3.4 mL in 237 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.3 mL in 237 mL
WATER (UNII: 059QF0KO0R)	43.7 mL in 237 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74358-0001-1	237 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	03/25/2020	

Labeler - Nittany Valley Distilling, LLC (085896519)

Registrant - Nittany Valley Distilling, LLC (085896519)

Establishment

Name	Address	ID/FEI	Business Operations
Nittany Valley Distilling, LLC		085896519	manufacture(74358-0001)

Revised: 3/2020

Nittany Valley Distilling, LLC