

S AND B FARMSTEAD HAND SANITIZER- s and b farms tead distillery hand sanitizer liquid

S&B Farmstead 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.

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	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
Use[s]	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	

Purpose

Antiseptic, Hand Sanitizer

Use

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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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Package Label - Principal Display Panel

000 mL NDC: 00000-000-00



Alcohol Antiseptic 80%
Hand Sanitizer

Topical Solution
Non-sterile Solution

18,927.1 mL

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74329-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	15141.68 mL in 18927.1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	2091.06 mL in 18927.1 mL
GLYCEROL FORMAL (UNII: 3L7GR2604E)	346.22 mL in 18927.1 mL

HYDROGEN PEROXIDE (UNII: BBX060AN9V)	875.43 mL in 18927.1 mL
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74329-0001-3	18927.1 mL in 1 PAIL; Type 0: Not a Combination Product	03/31/2020	
2	NDC:74329-0001-2	473.18 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2020	
3	NDC:74329-0001-4	59.15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/31/2020	

Labeler - S&B Farmstead Distillery (075464660)

Establishment

Name	Address	ID/FEI	Business Operations
S&B Farmstead Distillery		075464660	manufacture(74329-0001)

Revised: 3/2020

S&B Farmstead Distillery