

BLACKFORK SPIRITS, LLC HAND SANITIZER- alcohol liquid
BlackFork Spirits, 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.

Drug Facts	
Active Ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
Uses: Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
Flammable. Keep away from flames, fire or sparks.	
For external use only.	
Do not use:	
- On children less than 2 months of age.	
- On open skin wounds.	
When using this product	
Do not use in eyes, ears, and mouth. In case of contact with eyes rinse with water	
Stop use and ask doctor if	
irritation or redness develops or persists. These may be signs of a serious condition.	
Keep out of reach of children.	
If swallowed, get medical help or contact 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	
glycerol, hydrogen peroxide, Purified water USP	

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Manufactured by
BlackFork Spirits, LLC
Brandt, South Dakota, 57218

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

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Purpose

Antiseptic, Hand Sanitizer

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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.

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Package Label - Principal Display Panel

Clean-Job

HAND SANITIZER

Professional Grade

Non-steril Topical Solution

80% alcohol

18.9271 L NDC: 75093-001-01

473.12 mL NDC: 75093-001-02

946.24 mL NDC: 75093-001-01

Clean-Job HAND SANATIZER

Professional Grade
Non-steril Topical Solution

80% alcohol

5 U.S. GALLONS

Clean-Job HAND SANATIZER

Professional Grade
Non-steril Topical Solution

80% alcohol

16 Oz

Clean-Job HAND SANATIZER

Professional Grade
Non-steril Topical Solution

80% alcohol

32 Oz

BLACKFORK SPIRITS, LLC HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75093-001
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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75093-001-01	18927.1 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75093-001-02	473.12 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75093-001-03	946.24 mL in 1 BOTTLE, GLASS; 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 - BlackFork Spirits, LLC (117481909)

Registrant - BlackFork Spirits, LLC (117481909)

Establishment

Name	Address	ID/FEI	Business Operations
BlackFork Spirits, LLC		117481909	manufacture(75093-001)

Revised: 4/2020

BlackFork Spirits, LLC