

HAND SANITIZER- alcohol liquid
Foggy Mountain Spirit Company

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.

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Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Antiseptic Refill

Warnings

External use only. Do Not Ingest. Flammable. Keep away from flame. Keep Out Of Reach of Children. Do Not Use In or Near The Eyes. If Contact Occurs Flush 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.

Directions

- Place enough product in palm to thoroughly cover your hands. Rub together briskly until dry.
- Supervise children when using this product to avoid swallowing.

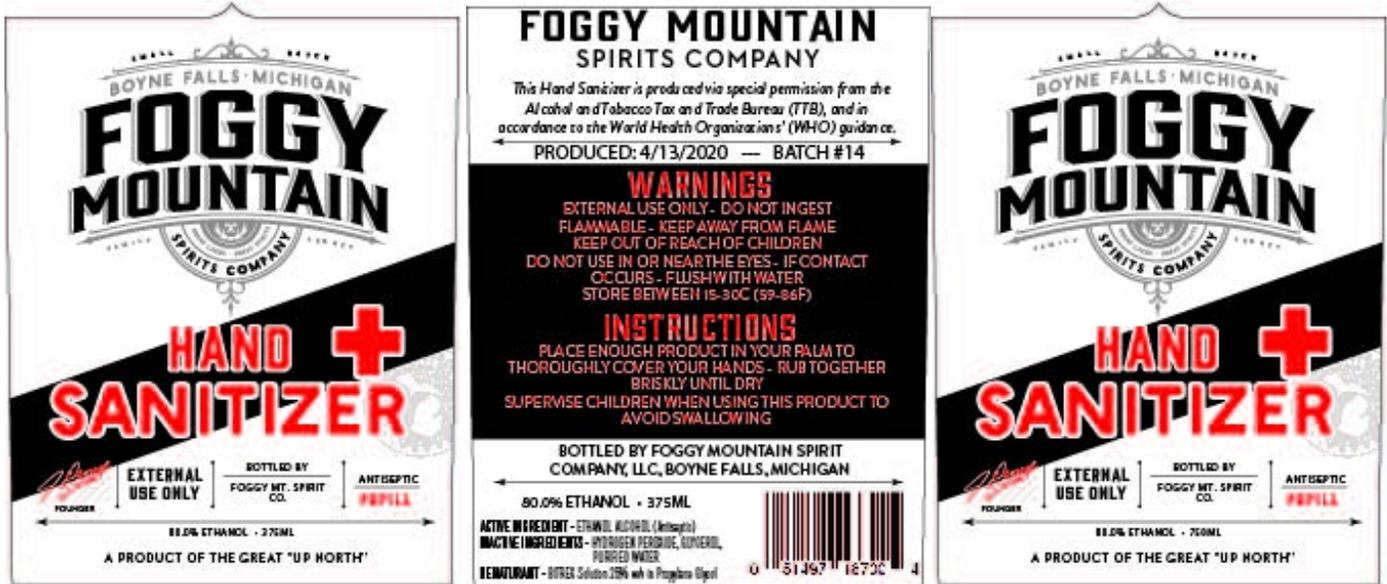
Other information

- Store between 15-30C (59-86F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water, BITREX (denaturant)

Package Label - Principal Display Panel



375 mL NDC: 74914-001-01

750 mL NDC: 74914-001-02

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74914-001
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:74914-001-01	375 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	04/01/2020	
2	NDC:74914-001-02	750 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	04/01/2020	
3	NDC:74914-001-03	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/05/2020	
4	NDC:74914-001-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2020	
5	NDC:74914-001-05	118 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	05/22/2020	
6	NDC:74914-001-06	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/01/2020	

Labeler - Foggy Mountain Spirit Company (117482006)**Establishment**

Name	Address	ID/FEI	Business Operations
Foggy Mountain Spirit Company		117482006	manufacture(74914-001)

Revised: 5/2020

Foggy Mountain Spirit Company