

MANNCAVE HAND SANITIZER- alcohol emulsion
SpikeWorld Enterprises Inc. dba MannCave Distilling

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

Purpose

Antiseptic, Hand Sanitizer

Use

Decreases bacteria on hands

Warnings

Flammable. Keep away from heat or flame. For external use only.

When using this product keep out of eyes and mouth.

Stop use and ask a doctor if irritation or redness develops.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- Rub a dime sized drop onto hands

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

236 mL NDC: 748248-001-02

Drug facts

Active IngredientPurpose

Alcohol 80%Antiseptic

USE: Decreases bacteria on hands

Warnings:

Flammable, Keep away from flame or high heat

For External Use Only.

When using this product keep out of eyes and mouth. Stop use and ask a doctor if irritation or redness develops.

www.manncave.com

Distiller of award winning craft WV spirits.

945 mL NDC: 748248-001-01



Alcohol Antiseptic
80%
Topical Solution
Non-sterile Solution
8oz / 236 ml

Be safe, sanitize.

Drug Facts (continued)

Keep out of reach of children.

If swallowed get medical help or contact a Poison Control Center right away.

Directions: Rub a dime sized drop into hands

Inactive ingredients: glycerin, hydrogen peroxide, purified water USP

Other Information: Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)

MannCave Distilling
851 Left Millstone Rd.
Weston, WV 26452
681-533-1001

Drug facts

Active IngredientPurpose

Alcohol 80%Antiseptic

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Distiller of award winning craft WV spirits.



MannCave Distilling Hand Sanitizer

Alcohol Antiseptic
80%
Topical Solution
Non-sterile Solution
32oz / 945 ml

Be safe, sanitize.

Drug Facts (continued)

Keep out of reach of children.

If swallowed get medical help or contact a Poison Control Center right away.

Directions: Rub a dime sized drop into hands

Inactive ingredients: glycerin, hydrogen peroxide, purified water USP

Other Information: Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)

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MANNCAVE HAND SANITIZER

alcohol emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74248-001
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: PDC6A3C00X)	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:74248-001-02	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	12/31/2023

2	NDC:74248-001-01	946 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	12/31/2023
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part333A		03/30/2020	12/31/2023

Labeler - SpikeWorld Enterprises Inc. dba MannCave Distilling (081368747)

Registrant - SpikeWorld Enterprises Inc. dba MannCave Distilling (081368747)

Establishment			
Name	Address	ID/FEI	Business Operations
SpikeWorld Enterprises Inc. dba MannCave Distilling		081368747	manufacture(74248-001)

Revised: 1/2021

SpikeWorld Enterprises Inc. dba MannCave Distilling