### SANIHOO HAND SANITIZER- alcohol liquid Red Barn Brands, 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.

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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

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

## Warnings

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

## 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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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.

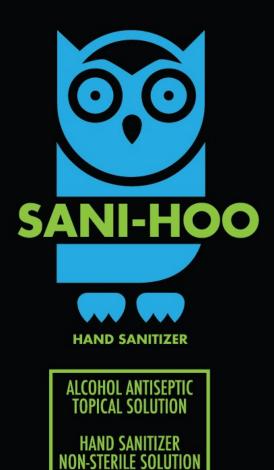
## Other information

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

# **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

# Package Label - Principal Display Panel



55-US GAL

Produced By: Red Barn Brands LLC Indianapolis, Indiana 46203





208198 mL NDC: 78888-080-55

# SANIHOO HAND SANITIZER

alcohol liquid

**Product Information** 

## DRUG FACTS

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

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Product Type							
		HUMAN OTC DRUG	Item Code	(Source)	N	DC:78888-080	
Route of Administr	ation	TOPICAL					
A	· / / A · · · · · · · · · · · · · · · ·						
Active Ingredient/Active Moiety					(a) 1		
Ingredient Name				<b>Basis of Strength</b>		Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)						80 mL in 100 mL	
Inactive Ingredi	ents						
Ingredient Name					Strength		
GLYCERIN (UNII: PDC6A3C0OX)					1.45 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)					0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)							
WATER (UNII: 059QI	F0KO0R)						
<b>WATER</b> (UNII: 059QI	F0 KO0 R)						
	F0 KO 0 R)						
Packaging	FOKOOR)	Package Description			ing Start	Marketing End	
Packaging		<b>Package Description</b> BOTTLE; Type 0: Not a Combi	inatio n		ate	Marketing End Date	
Packaging # Item Code	208198 mL in 1		inatio n	D	ate	U	
Packaging # Item Code	208198 mL in 1		ina tio n	D	ate	U	
<pre>Packaging # Item Code 1 NDC:78888-080- 55</pre>	208 198 mL in 1 Product		inatio n	D	ate	U	
Packaging # Item Code	208 198 mL in 1 Product formation			D 0 3/30 /20 20	pate	U	
Packaging # Item Code 1 NDC:78888-080- 55	208198 mL in 1 Product formation ory Applicat	BOTTLE; Type 0: Not a Combi	Citation M	D 0 3/30 /20 20	pate	Date	

Labeler - Red Barn Brands, LLC (087153900)

Establishment								
Name	Address	ID/FEI	Business Operations					
Red Barn Brands, LLC		087153900	manufacture(78888-080)					

Revised: 6/2020

Red Barn Brands, LLC