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.

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.

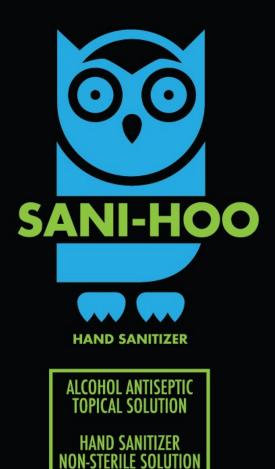
Other information

- 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



8-US OZ

Produced By: Red Barn Brands LLC Indianapolis, Indiana 46203





236.59 mL NDC: 78888-080-08

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)	NDC:78888-080		
Route of Administra	ation	TOPICAL					
Active Ingredient/Active Moiety							
Ingredient Name				Basis of Streng	th Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)				ALCOHOL	80 mL in 100 mL		
Inactive Ingradi	nto						
Inactive Ingredients Ingredient Name							
			Strength				
GLYCERIN (UNII: PDC	C6A3C0OX)	1.45 mL in 100 mL					
HYDRO GEN PERO XI		0 AN9 V)		0.125 mL in	100 mL		
		50 AN9 V)		0.125 mL in	100 mL		
HYDRO GEN PERO XI		50 AN9 V)		0.125 mL in	100 mL		
HYDROGEN PEROXI WATER (UNII: 059QF		50 AN9 V)		0.125 mL in	100 mL		
HYDRO GEN PERO XI		50 AN9 V)		0.125 mL in	100 mL		
HYDROGEN PEROXI WATER (UNII: 059QF		OAN9V) Package Description		0.125 mL in Marketing Start Date			
HYDROGEN PEROXI WATER (UNII: 059QF Packaging	OKOOR)		natio n 0	Marketing Start	Marketing End		
HYDROGEN PEROXI WATER (UNII: 059QF Packaging # Item Code	0KO0R) 236.59 mL in 1	Package Description	natio n 0	Marketing Start Date	Marketing End		
HYDROGEN PEROXI WATER (UNII: 059QF Packaging # Item Code	0KO0R) 236.59 mL in 1	Package Description	nation 0.	Marketing Start Date	Marketing End		
HYDROGEN PEROXI WATER (UNII: 059QF Packaging # Item Code	0KO0R) 236.59 mL in 1 Product	Package Description	nation 0.	Marketing Start Date	Marketing End		
HYDROGEN PEROXI WATER (UNII: 059QF Packaging # Item Code 1 NDC:78888-080- 08	0KO0R) 236.59 mL in 1 Product Cormation	Package Description	U.	Marketing Start Date	Marketing End Date		
Hybrogen peroxi wATER (UNII: 059QF P-ckaging f Item Code NDC:78888-080- 08	OKOOR) 236.59 mL in 1 Product Formation ry Applicat	Package Description BOTTLE; Type 0: Not a Combin	Citation Ma	Marketing Start Date 3/30/2020	Marketing End 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