

SANIHOO GEL HAND SANITIZER- gel hand sanitizer gel
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.

Active Ingredient(s)

Alcohol 69% 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

on 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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Directions

Place enough product on hands to cover all surfaces. Rub hands together to 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, carbomer, PEG-200, denatonium benzoate, triethanolamine

Package Label - Principal Display Panel

The label features a blue background with a pattern of white and light blue brush strokes. At the top left, the text 'HAND SANITIZER' is in large white letters, with 'GEL FORMULA' in green below it. In the center is a white owl logo with large eyes, and below it, the brand name 'SANI-HOO' in green. To the right, there are sections for 'DRUG FACTS', 'Warnings', 'Directions', and 'Other Information'. A vertical green warning 'DO NOT CONSUME!' is on the far right. At the bottom left is a white box with product details, and at the bottom right is a barcode with the number 78888-380-04 below it.

HAND SANITIZER

GEL FORMULA



SANI-HOO

DRUG FACTS

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ALCOHOL ANTISEPTIC
TOPICAL SOLUTION

HAND SANITIZER
NON-STERILE SOLUTION
4-US OZ



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78888-380-04

Produced By:
Red Barn Brands LLC
Indianapolis, IN 46203

118.294 mL NDC: 78888-380-04

SANIHOO GEL HAND SANITIZER

gel hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78888-380
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	69 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.5 mL in 100 mL
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.5 g in 100 mL
WATER (UNII: 059QF0KO0R)	24.75 mL in 100 mL
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	2 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.09 mL in 100 mL
CYMOPOGON CITRATUS LEAF (UNII: 06JMS448M5)	0.5 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78888-380-04	118.294 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/26/2020	

Labeler - Red Barn Brands, LLC (087153900)

Establishment

Name	Address	ID/FEI	Business Operations
Red Barn Brands, LLC		087153900	manufacture(78888-380)

Revised: 6/2020

Red Barn Brands, LLC