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 held 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

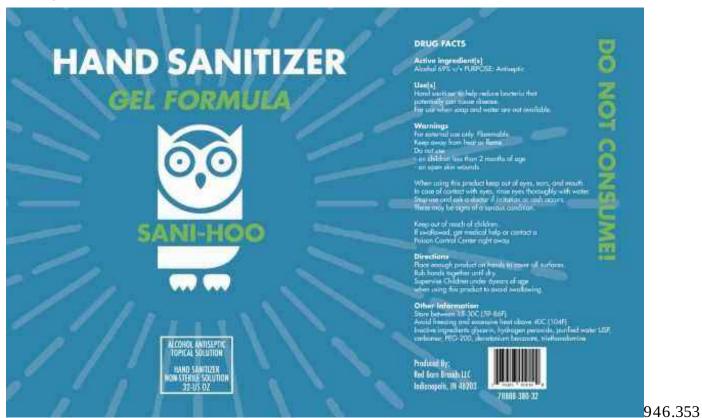
Store between 15-30C (59-86F)

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



mL NDC: 78888-380-32

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 HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	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: 903K93S3TK)	0.09 mL in 100 mL
CYMBOPOGON CITRATUS LEAF (UNII: 06JMS448M5)	0.5 mL in 100 mL
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:78888-38	946.353 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: 7/2020 Red Barn Brands, LLC