HAND SANITIZER- alcohol liquid SINGIN RIVER BREWING COMPANY

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.

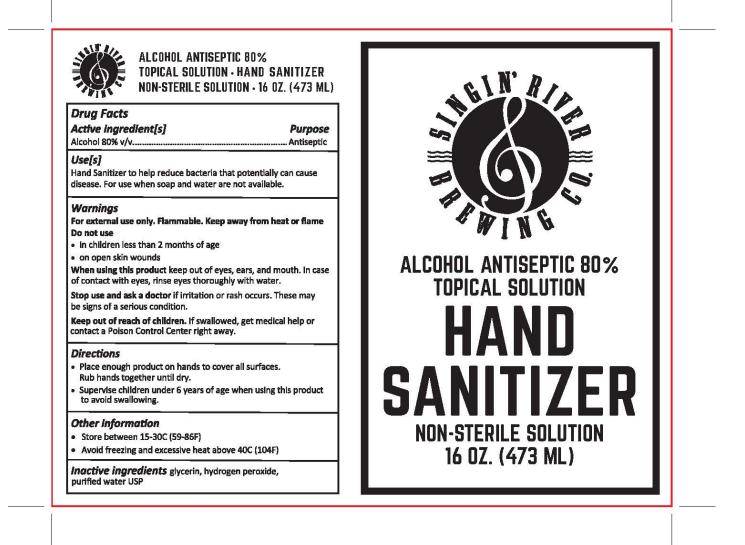
Other information

- 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



473 mL NDC: 74263-0001-2

HAND SANITIZER

alcohol liquid

Product Inform	ation						
Product Type		HUMAN OTC DRUG	Item Code	e (Source) 1	NDC:74263-0001	
Route of Administ	ration	TOPICAL					
Active Ingredie	nt/Active Moi	ety					
	Ingred	lient Name	Name Basis		of Strength	strength	
ALCOHOL (UNII: 3)	LCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL				80 mL in 100 mL		
Inactive Ingred							
Ingredient Name						Strength	
GLYCERIN (UNII: PDC6A3C0OX)					1.45 mL in 100 mL		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)					0.125 mL in 100 mL		
Packaging							
				Marketing Start		Marketing End	
# Item Code		Package Description		Date		Date	
1 NDC:74263- 0001-2	473 mL in 1 BOTT Product	LE, SPRAY; Type 0: Not a Com	binatio n	03/30/2	2020		
2 NDC:74263- 0001-1	263- 1892 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			03/30/2020			
Marketing In	nformation						
Marketing Category Applicat		ion Number or Monograph (Citation	Marketin	g Start Date	Marketing End Date	
OTC monograph not	final part333A		0	03/30/2020			

Labeler - SINGIN RIVER BREWING COMPANY (053909157)

Establishment									
Name	Address	ID/FEI	Business Operations						
SINGIN RIVER BREWING COMPANY		053909157	manufacture(74263-0001)						

Revised: 3/2020

SINGIN RIVER BREWING COMPANY