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.

Hand Santizer

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) (62%, 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 62% 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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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

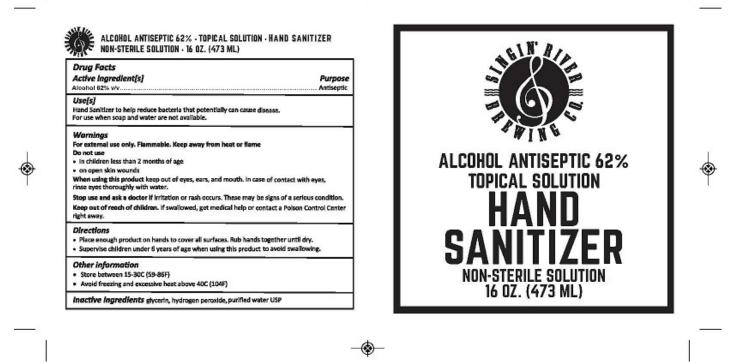
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

SRB_HandSanitizer_16ozLabels_62_65.qxp_SRB_HandSanitizer_16ozLabels_62_65 4/20/20 8:11 AM Page 1



474 mL NDC: 74263-0004-1

HAND SANITIZER alcohol liquid								
Product Information								
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:74263-0004					
Route of Administration	TOPICAL							
Active Ingredient/Active Moiety								

			Ingredient Name	Basis	of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)				ALCOHO	DL	62 mL in 100 mL	
In	nactive Ingred	lients					
Ingredient Name					Strength		
GLYCERIN (UNII: PDC6A3C0OX)					1.45 mL in 100 mL		
HYDROGEN PERO XIDE (UNII: BBX060AN9V)					0.125 mL in 100 mL		
W.	ATER (UNII: 059 Q	F0 KO	DR)				
Pa	ackaging						
#	Item Code		Package Description	Mar	keting Start Date	Marketing End Date	
	NDC:74263- 0004-3	947 n Produ	nL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Ict	04/20/2	2020		
	NDC:74263- 0004-1	474 m Produ	nL in 1 BOTTLE, PUMP; Type 0: Not a Combination act	04/20/2	2020		
-	NDC:74263- 0004-4	3786	mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2	2020		
	NDC-74262	1892	mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	04/20/2020			
1	NDC:74263- 0004-2	Pro du	ct	04/20/2	2020		
1				04/20/2	2020		
1			ict	04/20/2	2020		
4		Pro du		04/20/2	2020		
4 N .	0004-2	Produ 1fori	nation		g Start Date	Marketing End Dat	

Labeler - SINGIN RIVER BREWING COMPANY (053909157)

Establishment

Name	Address	ID/FEI	Business Operations
SINGIN RIVER BREWING COMPANY		053909157	manufacture(74263-0004)

Revised: 4/2020

SINGIN RIVER BREWING COMPANY