HAND SANITIZER- alcohol liquid Yahara Bay Distillers, Inc.

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 Sanitizer

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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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right 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

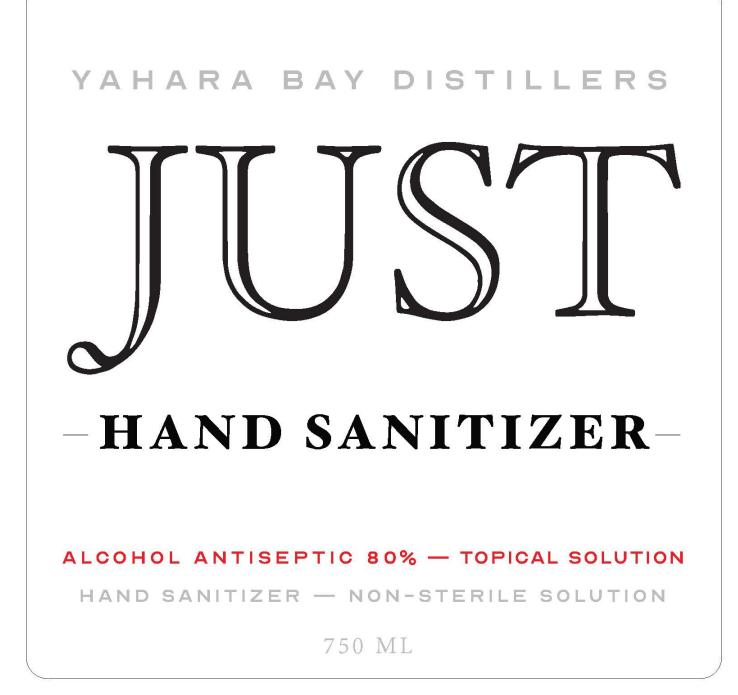
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

750 mL NDC: 77153-100-25



Drug Facts

Active Ingredient

Alcohol 80% v/v

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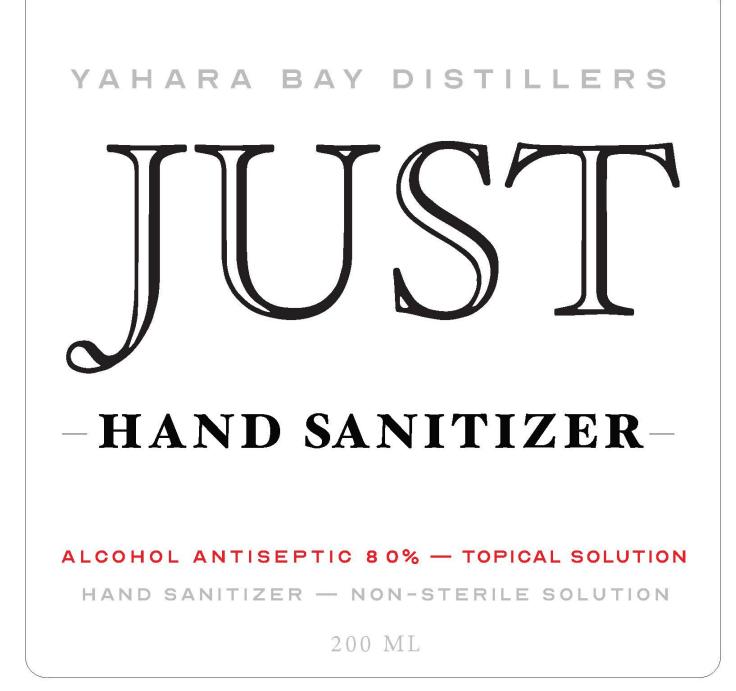
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NDC 77153-100-25

77153-100-67



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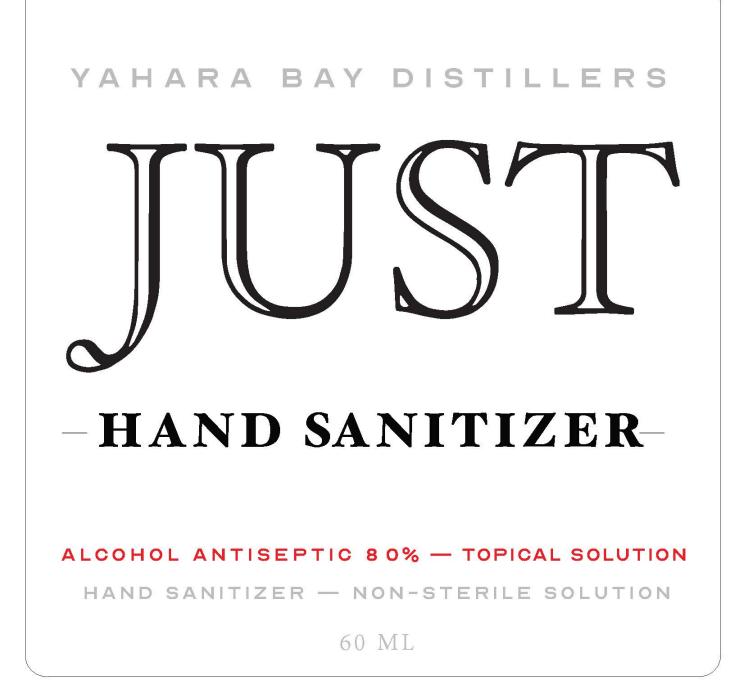
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NDC 77153-100-67

77153-100-60



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NDC 77153-100-60

HAND SANITIZER			
alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77153-100
Route of Administration	TOPICAL		
Active Ingredient/Active Moi	ety		
Ingred	lient Name	Basis of Strengt	h Strength
ALCOHOL (UNII: 3K9958V90M) (ALC	COHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL
Inactive Ingredients			

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: 059Q	F0KO	DR)					
Packaging								
#	Item Code		Package Description	Ma	rketing Start Date	Marketing End Date		
	NDC:77153-100- 25	750 m Produ	L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct	03/30	/2020			
2	NDC:77153-100- 67	200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		03/30	/2020			
	NDC:77153-100- 60	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		03/30/2020				
N	Iarketing In	ıforı	nation					
Marketing Category		ory	Application Number or Monograph Citation	Marketi	ng Start Date	Marketing End Dat		
1								

Labeler - Yahara Bay Distillers, Inc. (010304234)

Registrant - Yahara Bay Distillers, Inc. (010304234)

Establishment								
Name	Address	ID/FEI	Business Operations					
Yahara Bay Ditillers, Inc.		010304234	manufacture(77153-100)					

Revised: 5/2020

Yahara Bay Distillers, Inc.