MRDC HAND SANITIZER- alcohol liquid Mississippi River Distilling 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 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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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

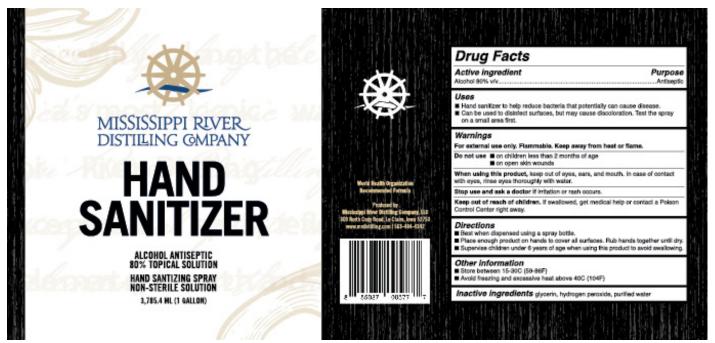
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

3785.41 mL NDC: 77236-001-02



208197.7

MISSISSIPPI RIVER DISTILLING GMPANY

ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION

HAND SANITIZER NON-STERILE SOLUTION

208.2 L (55 GALLON)

Active ingredient(s) Alcohol 80% v/v	Purpose Antiseptio
Use[s] Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap	and water are not available.
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

PRODUCED BY

MISSISSIPPI RIVER DISTILLING COMPANY, LLC 303 NORTH CODY ROAD, LE CLAIRE, IOWA 52753 WWW.MRDISTILLING.COM - 563-484-4342

208197.7mL NDC: 77236-001-01

MRDC HAND SANITIZER

alcohol liquid

Product Information						
Product T ype	HUMAN OTC DRUG	OTC DRUG Item Code (Source)		NI	NDC:77236-001	
Route of Administration	TOPICAL					
Active Ingredient/Active Moi	etv					
•	lient Name		Basis of Stre	ength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALC	COHOL - UNII:3K9958V90M		ALCOHOL		80 mL in 100 mL	
Inactive Ingredients						
Inactive Ingredients	gredient Name			St	rength	
Inactive Ingredients In				St in 100 n	rength	
Inactive Ingredients	gredient Name		1.45 mL		r ength nL	
Inactive Ingredients In GLYCERIN (UNII: PDC6A3C0OX) HYDROGEN PEROXIDE (UNII: BBX06	gredient Name		1.45 mL	in 100 n	r ength nL	
Inactive Ingredients In GLYCERIN (UNII: PDC6A3C0OX)	gredient Name		1.45 mL	in 100 n	r ength nL	
Inactive Ingredients In GLYCERIN (UNII: PDC6A3C0OX) HYDROGEN PEROXIDE (UNII: BBX06	gredient Name		1.45 mL	in 100 n	r ength nL	

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:77236-001-01	208197.7 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77236-001- 02	3785.41 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
N	/Iarketing Inf	formation		
	Marketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
0	TC monograph not fi	nal part333A	03/30/2020	

Labeler - Mississippi River Distilling Company (053522931)

Registrant - Mississippi River Distilling Company (053522931)

Establishment

Name	Address	ID/FEI	Business Operations
Mississippi River Distilling Company		053522931	manufacture(77236-001)

Revised: 5/2020

Mississippi River Distilling Company