

GARRISON BROTHERS DISTILLERY HAND SANITIZER- garrison brothers hand sanitizer liquid

Garrison Brothers Distillery

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 Ingredients & back label [OTC - ACTIVE INGREDIENT SECTION]

Alcohol 80% v/v. Purpose: Antiseptic

COMPOSITION: ethanol or isopropanol, glycerol and hydrogen peroxide. WHO-RECOMMENDED HANDRUB FORMULATION: Whitedog (ethanol) – 80% volume/volume, Glycerol (1.45% v/v), Hydrogen peroxide (.125% v/v), boiled rainwater. FOR EXTERNAL USE ONLY: Avoid contact with eyes. Keep out of reach of children. FLAMMABLE: Keep away from flame and heat. USE: Apply a palmful of alcohol-based hand rub and cover all surfaces of the hands. Rub hands until dry.

Purpose

Use(s)

Hand Sanitizer to help reduce bacteria that potentially cause disease. For use when soap and water are not available.

Use

Uses: Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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.

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.

Do not use

- in children less than 2 months of age
- on open skin wounds

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Directions

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- 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

WASH YOUR DAMN HANDS



COMPOSITION: ethanol or isopropanol, glycerol and hydrogen peroxide.

WHO-RECOMMENDED HANDRUB FORMULATION: Whitedog (ethanol) – 80% volume/volume, Glycerol (1.45% v/v), Hydrogen peroxide (.125% v/v), boiled rainwater.

FOR EXTERNAL USE ONLY: Avoid contact with eyes. Keep out of reach of children.

FLAMMABLE: Keep away from flame and heat. **USE:** Apply a palmful of alcohol-based handrub and cover all surfaces of the hands. Rub hands until dry.

DATE:

BATCH:

120ML 77293-0001-1 NDC

COMPOSITION: ethanol or isopropanol, glycerol and hydrogen peroxide. WHO-RECOMMENDED

HANDRUB FORMULATION: Whitedog (ethanol) – 80% volume/volume, Glycerol (1.45% v/v), Hydrogen peroxide (.125% v/v), boiled rainwater. FOR EXTERNAL USE ONLY: Avoid contact with eyes. Keep out of reach of children. FLAMMABLE: Keep away from flame and heat. USE: Apply a palmful of alcoholbased handrub and cover all surfaces of the hands. Rub hands until dry.

WASH YOUR DAMN HANDS

DATE: BATCH:

GARRISON BROTHERS DISTILLERY HAND SANITIZER

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77293-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	141.6 mL in 177 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCEROL FORMAL (UNII: 3L7GR2604E)	2.57 mL in 177 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.23 mL in 177 mL
WATER (UNII: 059QF0KO0R)	32.6 mL in 177 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77293-0001-3	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77293-0001-2	750 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77293-0001-1	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Garrison Brothers Distillery (043768088)

Establishment

Name	Address	ID/FEI	Business Operations
Garrison Brothers Distillery		043768088	manufacture(77293-0001)

Revised: 5/2020

Garrison Brothers Distillery