SEVEN THREE HAND SANITIZER- alcohol antiseptic 80% liquid Seven Three Distilling Company, LLC

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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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

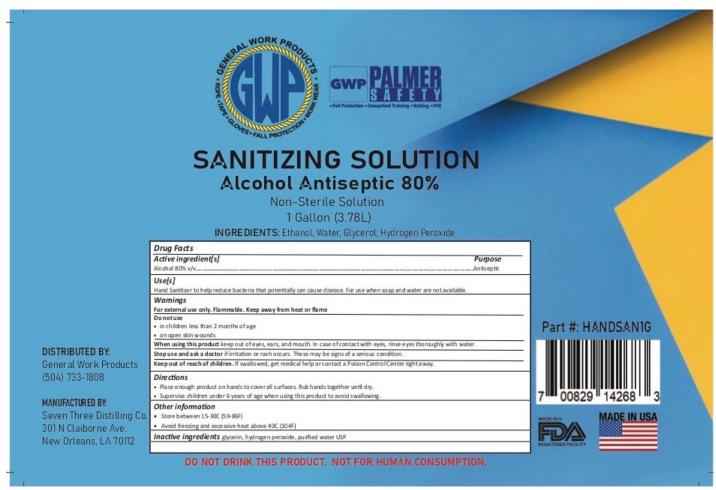
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

3785 mL NDC: 75219-7733-1



100 mL NDC: 75219-7733-2

100 ml 3.4 fl oz BY: PROFESSIONAL IMAGE • (985) 649-5145 BY: SEVEN THREE DISTILLING CO., 301 N CLAIBORNE AVE. NEW ORLEANS, LA 70112 **Drug Facts** Active ingredient Purpose Ethyl Alcohol 80%. Antiseptic Use • for handwashing to decrease bacteria on the skin * recommended for repeated use For external use only-hands Logo Here Flammable. Keep away from heat and flame. When using this product + keep out of eyes. In case of contact with eyes, flush thoroughly with water + avoid contact with broken skin + do not inhale or ingest Stop use and ask doctor if skin irritation develops. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Directions • wet hands thoroughly with product and allow to dry without wiping + for children under 6, use only under adult supervision + not recommended DISTRIBUTED MANUFACTURED Other Information • do not store above 105°F • may discolor some fabrics • harmful to wood finishes and plastics HAND SANITIZER Inactive ingredients • purified water USP, glycerin, hydrogen peraxide EFFECTIVE AT ELIMINATING 99.99% OF MANY COMMON MADE IN USA HARMFUL GERMS & BACTERIA IN AS LITTLE AS 15 SECONDS.

3785 mL NDC: 75219-7733-3

1 GALLON

Drug Facts:

Active layer (4.4.

Active layer



DISTRIBUTED BY: EAGLE INDUSTRIES New Orleans, LA 70123 800-266-8246 www.eagleind.com

HAND SANITIZER SOLUTION

MANUFACTURED BY: SEVEN THREE DISTILLING CO. New Orleans, LA 70112





Alcohol Antiseptic 80% Topical Solution

> Sanitizing Solution Non-Sterile Solution 1 Gallon (3.78L)



DO NOT DRINK THIS PRODUCT. NOT FOR HUMAN CONSUMPTION.

SEVEN THREE HAND SANITIZER

alcohol antiseptic 80% liquid

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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:75219-7733

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

Maybeting Start Maybeting End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75219 - 7733-1	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75219 - 7733-2	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75219 - 7733-3	3785 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 - Seven Three Distilling Company, LLC (087822184)

Establishment					
Name	Address	ID/FEI	Business Operations		
Seven Three Distilling Company, LLC		087822184	manufacture(75219-7733)		

Revised: 2/2021 Seven Three Distilling Company, LLC