

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)

Ethyl Alcohol 80% v/v. Purpose: Antiseptic

Hydrogen Peroxide <1% 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.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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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

water, glycerin, lemongrass oil

Package Label - Principal Display Panel

100 mL NDC: 75219-3700-1

3.4 FL OZ 100 ML

BOTTLED BY SEVEN THREE
DISTILLING COMPANY, NEW ORLEANS, LA

NEW ORLEANS

SEVEN THREE
DISTILLING CO.

LEMONGRASS CITRUS
HAND SANITIZER*

EFFECTIVE AT ELIMINATING 99.99% OF MANY COMMON HARMFUL GERMS & BACTERIA IN AS LITTLE AS 15 SECONDS.

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Drug Facts	
Active ingredient	Purpose
Ethyl Alcohol 80%.....	Antiseptic
Hydrogen Peroxide <1%.....	Antiseptic
Uses • for handwashing to decrease bacteria on the skin • recommended for repeated use	
Warnings For external use only-hands 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 a 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 for infants	
Other information • do not store above 105°F • may discolor some fabrics • harmful to wood finishes and plastics	
Inactive ingredients • water, glycerin, lemongrass oil	

VISIT SEVEN THREE DISTILLING CO. @ 301 N CLAIBORNE AVE, NEW ORLEANS, LA 70112
OR ONLINE AT SEVENTHREEDISTILLING.COM OR CALL (504) 265-8545

SEVEN THREE HAND SANITIZER

alcohol antiseptic 80% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75219-3700
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	0.125 mL in 100 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)	0.002 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75219-3700-1	100 mL in 1 BOTTLE, SPRAY; 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(75219-3700)

Revised: 2/2021

Seven Three Distilling Company, LLC