

SEVEN THREE HAND SANITIZER- alcohol antiseptic 70% gel
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) (70%, 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.
- e. Methacrylic Acid - Ethyl Acrylate Copolymer (5.5% v/v)

The firm does add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Ethanol 70%. Purpose: Antiseptic

Hydrogen Peroxide <1%. Purpose: Antiseptic

DISTILLED & BOTTLED BY SEVEN THREE
DISTILLING COMPANY, NEW ORLEANS, LA

128 FL OZ

3785 ML



GEL HAND SANITIZER LEMONGRASS CITRUS

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

Drug Facts

Active ingredient	Purpose
Ethanol 70%	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.

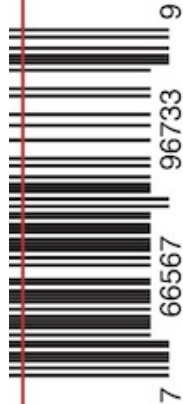
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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, carbopol, 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



Use

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Purpose

Antiseptic, Hand Sanitizer

Package Label - Principal Display Panel

128 FL OZ (3785ML) 75219-7300-1

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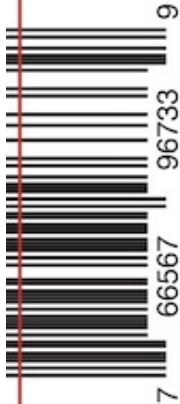
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SEVEN THREE HAND SANITIZER

alcohol antiseptic 70% gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75219-7300
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	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)	0.002 mL in 100 mL
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	5.5 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75219-7300-1	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2020	

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(75219-7300)

Revised: 2/2021

Seven Three Distilling Company, LLC