

**HAND SANITIZER- alcohol liquid**  
**Virus Protection Systems 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.*

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**Steve Madden Label 70% Alcohol Hand Sanitizer, 30ML**

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 (70%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (.4% v/v).
- c. Hydrogen peroxide (0.4% 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 70% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

For hand-washing to decrease bacteria on the skin if soap and water is not available

Back of the bottle



## Warnings

Flammable. Keep away from heat or flame

## Do not use

in or near the eyes

Stop use and ask a doctor if irritation or redness develop.

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

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## Directions

- Wet hands thoroughly with product and rub together and allow to dry without wiping

## Other information

- Store below 105 fahrenheit

- May discolor some fabrics

**Inactive ingredients**

Water, glycerin, carbomer, triethanolamine, denatonium, benzoate

**Package Label - Principal Display Panel**

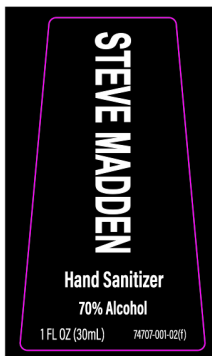
Steve Madden

Hand Sanitizer

70% Alcohol

30 ml NDC: 74707-001-03

25x45mm



<b>HAND SANITIZER</b>			
alcohol liquid			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74707-001
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.4 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.4 mL in 100 mL
WATER (UNII: 059QF0K00R)	29.2 mL in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74707-001-03	30 mL in 1 BOTTLE; 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** - Virus Protection Systems LLC (117475374)**Establishment**

Name	Address	ID/FEI	Business Operations
VIRUS PROTECTION SYSTEMS, LLC		117475374	relabel(74707-001)

Revised: 5/2020

Virus Protection Systems LLC