

**HAND SANITIZER- alcohol spray**  
**MAESA 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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**Refine Purify Unscented Instant Hand Sanitizer**

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 (75%, 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. 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 75% 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

<b>UNSCENTED INSTANT HAND SANITIZER SPRAY</b> Alcohol 75% Non-Sterile Liquid	<b>Drug Facts:</b>	<b>Drug Facts (continued)</b>
	<b>Active Ingredients</b> Alcohol 75% v/v.....Antiseptic	<b>Purpose</b> Antiseptic
<b>REFINE PURIFY</b>	<b>Uses:</b> <ul style="list-style-type: none"><li>• Hand sanitizer to help reduce bacteria that potentially can cause disease.</li><li>• For use when soap and water are not available.</li></ul>	<b>Directions:</b> <ul style="list-style-type: none"><li>• Put enough product in your palm to cover hands and rub hands together until dry.</li><li>• Children under 6 years of age should be supervised when using this product.</li></ul>
	<b>Warnings:</b> <ul style="list-style-type: none"><li>• Flammable.</li><li>• Keep away from fire or flame.</li><li>• For external use only.</li><li>• Do not use<ul style="list-style-type: none"><li>• In children less than 2 months of age.</li><li>• On open skin wounds.</li></ul></li><li>• When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask doctor if irritation or rash appears and lasts.</li><li>• Keep out of reach of children.</li><li>• If swallowed, get medical help ►</li></ul>	<b>Other Information:</b> <ul style="list-style-type: none"><li>• Store between 59 - 86°F (15 - 30°C).</li><li>• Avoid freezing and excessive heat above 104°F (40°C).</li><li>• May discolor certain fabric surfaces.</li></ul> <b>Inactive Ingredients:</b> Water.
100 mL / 3.4 FL. OZ.		<b>Questions, Comments:</b> YOU MAY REPORT AN ADVERSE REACTION TO: MAESA LLC C/O REPORT REACTION LLC, PO BOX 22, PLAINSBORO, NJ 08536-0222.
		DISTRIBUTED BY: MAESA LLC 225 LIBERTY STREET, NEW YORK, NY 10281. MADE IN CHINA
	MSRP: \$6.00	

100 mL NDC: 71899-100-00

## HAND SANITIZER

alcohol spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71899-100
<b>Route of Administration</b>	TOPICAL, EXTRACORPOREAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL
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### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

### Product Characteristics

Color	white (Transparent)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71899-100-00	100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/22/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/22/2020	

**Labeler** - MAESA LLC (144282311)