

## **HAND SANITIZER- alcohol spray**

**Jon Davler, Inc.**

*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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### **Kenia Ontiveros SPRAY Hand Sanitizer 100ml**

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 70% 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.

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

### 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 (aqua), Isopropyl Alcohol, Glycerin, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Fragrance.

### Package Label - Principal Display Panel

100mL NDC: 74044-0050-3



KENIA ONTIVEROS  
BEAUTY

ALOE VERA  
& VITAMIN E

**PRETTY & CLEAN**  
Alcohol spray

**70% Ethyl Alcohol**  
(CDC recommends 60%+)

**SWEET PEONY**

MADE IN USA  
3.4 FL. OZ. (100 mL)

### Drug Facts

<b>Active Ingredient</b> Ethyl Alcohol 70%	<b>Purpose</b> Antimicrobial
<b>Uses</b> <ul style="list-style-type: none"><li>• Hand sanitizer to help reduce bacteria on skin that could cause disease.</li><li>• Recommended for repeated use.</li></ul>	
<b>Warnings</b> <p><b>Flammable.</b> Keep away from fire or flame.</p> <p><b>For external use only</b></p> <p>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 a doctor if irritation or rash appears and lasts.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p>	
<b>Directions</b> <ul style="list-style-type: none"><li>• Place enough product in your palm to thoroughly cover your hands.</li><li>• Rub hands together briskly until dry.</li><li>• No rinsing required • No towels needed.</li></ul>	
<b>Other information</b> <ul style="list-style-type: none"><li>• Do not store above 110°F (43°C).</li><li>• May discolor certain fabrics or surfaces.</li></ul>	
<b>Inactive ingredients</b> Water (aqua), Isopropyl Alcohol, Glycerin, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Fragrance.	

**crucityfree andvegan**

NDC# 74044-0050-3  
LOT# 0525B3  
EXP: 06/2022

**Distributed by:**  
KENIA ONTIVEROS BEAUTY LLC,  
Los Angeles, CA 91706.

**Kenia Beauty**  
@KeniaOBauty  
WWW.KENIABEAUTY.COM

## HAND SANITIZER

alcohol spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74044-0050
<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)	0.036 mL in 100 mL
ALOE (UNII: V5VD430YW9)	0.13 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74044-0050-3	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/06/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/06/2020	

**Labeler** - Jon Davler, Inc. (097710185)

Establishment			
Name	Address	ID/FEI	Business Operations
Jon Davler, Inc.		097710185	manufacture(74044-0050)

Revised: 5/2020

Jon Davler, Inc.