

## **HAND SANITIZER- alcohol spray**

### **Olivia Care**

*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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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. 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 80% 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, purified water USP

## Package Label - Principal Display Panel

5.19" x 2.362

The image shows the principal display panel of an Olivia Care Hand Sanitizer label. The label is rectangular with a white background and purple accents. At the top left, it says 'OLIVIA CARE™ SINCE 1996'. Below that, in a purple box, it says 'ALL NATURAL HAND SANITIZER'. To the right of this box, there is a paragraph describing the product as a natural ingredient hand sanitizer that kills 99.9% of germs. Below this, it says 'crafted in CA, USA for quick on-the-go clean!' and 'vegan, cruelty free, no sulfates or parabens.' At the bottom left, it says 'PURIFYING LAVENDER' and '4 fl oz / 118 mL'. On the right side, there is a 'Drug Facts' section with a table of ingredients and their purposes, and a list of warnings and directions. The label also features several icons: a leaf, a recycling symbol, a 'NO PARABENS SULFATES' icon, a 'VEGAN PRODUCT' icon, and a 'Cruelty Free' icon. A barcode is located at the bottom right of the label.

MANUFACTURED & DISTRIBUTED BY OLIVIA CARE, INC. ALL RIGHTS RESERVED.

OLIVIA CARE™  
SINCE 1996

**ALL NATURAL  
HAND SANITIZER**

Our natural ingredient hand sanitizer utilizes germ-killing ethyl alcohol. Crafted with care, this sanitizer is perfect for quick use. A simple clean when you aren't near soap and water.

crafted in CA, USA for quick **on-the-go** clean!

vegan, cruelty free, no sulfates or parabens.

**effectively kills 99.9% of germs.**

**PURIFYING  
LAVENDER**

4 fl oz / 118 mL

PARABENS  
SULFATES  
FREE

VEGAN  
PRODUCT

73739

8 50005 14057 9

**Drug Facts**

Active Ingredient	Purpose
Ethyl Alcohol 62%	Antiseptic

**Uses** for hand washing to decrease bacteria on skin.

**Warning:** For external use only. Flammable. Keep away from fire or flame.

**Do not use** near eyes. In case of contact rinse eyes thoroughly with water.

**Stop use and ask 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:** Spray on palm and rub hands together. Supervise children under 6.

**Inactive Ingredients:** Aqua (Water), Glycerin, Parfum (Fragrance).

**Other information** Store at 20°C – 25°C (68°F – 77°F).

**Questions?** Call 1-888-965-4842

5.19" x 2.362



118 mL NDC: 73739-001-04

## HAND SANITIZER

alcohol spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73739-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
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:73739-001-04	118 mL in 1 BOTTLE, PLASTIC; 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** - Olivia Care (799881644)

## Establishment

Name	Address	ID/FEI	Business Operations
Olivia Care		799881644	manufacture(73739-001)

Revised: 4/2020

Olivia Care