

## **HAND SANITIZER- alcohol gel**

**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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### **LASplash So Fresh Peppermint Gel Hand Sanitizer**

**74044-1009-4 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, Propylene Glycol, Glycerin, Peg-6 (and) AMP-Acrylates/Vinyl Isodecanoate Crosspolymer, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Mentha Piperita (Peppermint) Oil.

**Package Label - Principal Display Panel**

100 mL NDC: 74044-1009-4

Active Ingredient	Purpose
Ethyl Alcohol 70% .....	Antimicrobial

**Warnings**  
**Flammable.** Keep away from fire or flame.  
**For external use only:** • Do not use product in or near the eyes. In case of contact, rinse eyes thoroughly with water • Stop use & ask a doctor if irritation or rash appears & lasts.  
**Keep our of reach of children.** Do not ingest. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions:**  
 • Place product in your palm to thoroughly cover your hands.  
 • Rub hands together briskly until dry.  
 • No rinsing required.

**Other information**  
 • Do not store above 110°F (43°C).  
 • May discolor certain fabrics or surfaces.

**Inactive ingredients:** Water (aqua), Isopropyl Alcohol, Propylene Glycol, Glycerin, Peg-6 (and) AMP-Acrylates/ Vinyl Isodecanoate Crosspolymer, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Mentha Piperita (Peppermint) Oil.

Hand Sanitizer PM  
 8 71923 00098 5  
 NDC# 74044-1009-4 LOT# 06BJ-3 EXP: 06/2022

Manufactured by JON DAVLER, INC.  
 9440 Gidley Street, Temple City, CA 91780, USA.  
 LASplashCosmetics.com  
 crutivityfree andvegan

**HAND SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74044-1009	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	70 mL in 100 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
GLYCERIN (UNII: PDC6A3C0OX)			0.451 mL in 100 mL	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			0.677 mL in 100 mL	
WATER (UNII: 059QF0K00R)				
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)			2.821 mL in 100 mL	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)			0.094 mL in 100 mL	
ALOE (UNII: V5VD430YW9)			0.094 mL in 100 mL	
MENTHA PIPERITA (UNII: 79M2M2UDA9)			0.142 mL in 100 mL	
ISOPROPYL ALCOHOL (UNII: ND2M416302)			6.996 mL in 100 mL	
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:74044-1009-4	100 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/01/2020	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part333A	06/01/2020		

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

### Establishment

Name	Address	ID/FEI	Business Operations
Jon Davler, Inc.		097710185	manufacture(74044-1009)

Revised: 6/2020

Jon Davler, Inc.