

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.

LASplash 70%+ all-in-one Lavender Sanitizing Spray 90ml

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.

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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

Water (aqua), Isopropyl Alcohol, Glycerin, Aloe Barbadosensis Leaf Juice, Tocopheryl Acetate, Lavandula Angustifolia (Lavender) Flower Oil.

Package Label - Principal Display Panel

90 mL NDC: 74044-1004-3

So Fresh & So Clean Lavender

LASplash cosmetics

all-in-one sanitizing spray

This bottle belongs to

- + Spray on hands
- + Spray on clothing
- + Spray on door handles
- + Spray on masks
- + Spray fresh & stay clean

70%+
Ethyl Alcohol
Kills Germs

MADE IN USA
3 fl. oz. (90ml)

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70%	Antimicrobial

Uses

- Disinfect hands and common household surfaces.

Warnings

Flammable. Keep away from fire or flame.

For external use only. 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.

Keep out of reach of children. Do not ingest. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Spray on hands and rub until dry.
- Spray on any surfaces and wipe clean.
- 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, Glycerin, Aloe Barbadosensis Leaf Juice, Tocopheryl Acetate, Lavandula Angustifolia (Lavender) Flower Oil.

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

#11004 SANITIZING SPRAY LV
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LOT# 06BU-4 EXP: 06/2022

NDC# 74044-1004-3

HAND SANITIZER			
alcohol spray			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74044-1004

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65.835 mL in 100 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	4.993 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	0.143 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.03 mL in 100 mL
ALOE (UNII: V5VD430YW9)	0.02 mL in 100 mL
WATER (UNII: 059QF0K00R)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	0.02 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74044-1004-3	90 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/15/2020	

Labeler - Jon Davler, Inc. (097710185)

Establishment

Name	Address	ID/FEI	Business Operations
Jon Davler, Inc.		097710185	manufacture(74044-1004)

Revised: 5/2020

Jon Davler, Inc.