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 Orange Creamsicle 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), Isoporopyl Alcohol, Glycerin, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Fragrance.

Package Label - Principal Display Panel



HAND SANITIZER alcohol spray Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:74044-1006

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
	ISOPROPYL ALCOHOL	4.995 mL in 100 mL	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65.859 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
CITRUS AURANTIUM FRUIT O IL (UNII: 59JDQ5VT0T)	0.107 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)	0.03 mL in 100 mL		
ALOE (UNII: V5VD430 YW9)	0.02 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			
.ALPHATO COPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	0.02 mL in 100 mL		

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:74044-1006-	90 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/18/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/18/2020		

Labeler - Jon Davler, Inc. (097710185)

Establishment			
Name	Address	ID/FEI	Business Operations
Jon Davler, Inc.		097710185	manufacture(74044-1006)

Revised: 5/2020 Jon Davler, Inc.