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 Clear Mind 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 65.8% v/v. Purpose: Antiseptic

Isopropyl Alcohol 4.9% 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), Glycerin, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Mentha Piperita (Peppermint) Oil, Citrus Medica Limonum (Lemon) Peel Oil, Lavandula Angustifolia (Lavender) Flower Oil.

Package Label - Principal Display Panel

90 mL NDC: 74044-1003-3



HAND SANITIZER alcohol spray

Product Information	n				
Product T ype	HUMAN OTC DRUG	HUMAN OTC DRUG Item Code (Source)		NDC:74044-1003	
Route of Administration	on TOPICAL				
Active Ingredient/A	Active Moiety				
Ingredient Name			Basis of Strengt	h Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)		LCOHOL -	ISOPROPYL ALCOHOL	4.986 mL in 100 mL	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL			ALCOHOL	65.742 mL in 100 mL	
Inactive Ingredient	ts				
Ingredient Name				Strength	
.ALPHATO COPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)			0.02 mL	0.02 mL in 100 mL	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19 AH1RAF4M)			0.107 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)			0.03 mL in 100 mL		
ALOE (UNII: V5VD430YW9)			0.02 mL in 100 mL		
WATER (UNII: 059QF0K					
CITRUS MEDICA FRUIT (UNII: ZE5Q6PN9ON)			0.107 mL in 100 mL		
MENTHA PIPERITA (UNII: 79 M2M2UDA9)			0.036 m	L in 100 mL	
Packaging		Marketing Start	Marketing End		
# Item Code	Package Description) n	Date	Date	
1NDC:74044-1003- 390 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product10/16/20		10/16/2020			
Marketing Info	rmation				
Marketing Category	Application Number or Mono	graph Citation M	arketing Start Date	Marketing End Da	
	part333A		/16/2020		

Labeler - Jon Davler, Inc. (097710185)

 Name
 Address
 ID/FEI
 Business Operations

 Jon Davler, Inc.
 097710185
 manufacture(74044-1003)

Revised: 10/2020