#### FLYGIENE NOURISHING HAND SANITIZER- alcohol gel FLYGIENE LLC

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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) (70%, 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. 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

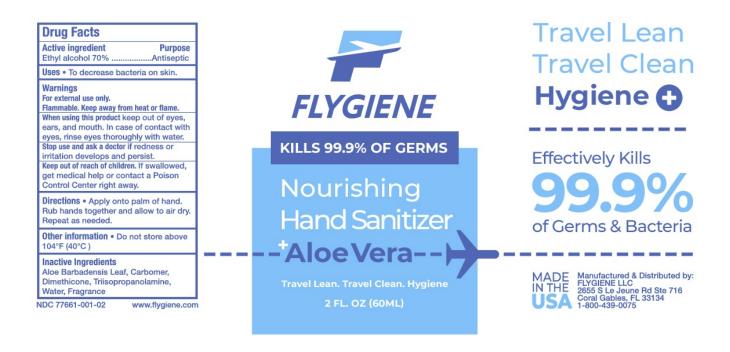
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

### **Inactive ingredients**

carbomer homopolymer, unspecified type, aloe vera leaf, dimethicone, triisopropanolamine, purified water usp

#### Package Label - Principal Display Panel

60 mL NDC: 77661-001-02



# Product Type HUMAN OTC DRUG FLYGIENE NOURISHING HAND SANITIZER alcohol gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:77661-001

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<b>Active</b>	Ingredient/Active	Moiety
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Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive	Ingredients
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Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)		
TRIISOPROPANOLAMINE (UNII: W9EN9DLM98)		
WATER (UNII: 059QF0KO0R)		

## **Packaging**

	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:77661-001-	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/21/2020	

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M003	05/21/2020	
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# Labeler - FLYGIENE LLC (117528741)

# **Establishment**

Name	Address	ID/FEI	<b>Business Operations</b>	
FLYGIENE LLC		117528741	manufacture(77661-001)	

Revised: 1/2024 FLYGIENE LLC