

FLYGIENE NOURISHING HAND SANITIZER- alcohol gel

FLYGIENE LLC

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.

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

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

Package Label - Principal Display Panel

60 mL NDC: 77661-001-02

Drug Facts	
Active ingredient	Purpose
Ethyl alcohol 70%	Antiseptic
Uses • To decrease bacteria on skin.	
Warnings	
For external use only.	
Flammable. Keep away from heat or flame.	
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 redness or irritation develops and persist.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions • Apply onto palm of hand. Rub hands together and allow to air dry. Repeat as needed.	
Other information • Do not store above 104°F (40°C)	
Inactive Ingredients	
Aloe Barbadensis Leaf, Carbomer, Dimethicone, Triisopropanolamine, Water, Fragrance	
NDC 77661-001-02	www.flygiene.com



FLYGIENE

KILLS 99.9% OF GERMS

Nourishing Hand Sanitizer

+Aloe Vera-

Travel Lean. Travel Clean. Hygiene

2 FL. OZ (60ML)

Travel Lean
Travel Clean
Hygiene +

Effectively Kills
99.9%
of Germs & Bacteria

MADE IN THE USA Manufactured & Distributed by:
FLYGIENE LLC
2655 S Le Jeune Rd Ste 716
Coral Gables, FL 33134
1-800-439-0075

FLYGIENE NOURISHING HAND SANITIZER

alcohol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:77661-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77661-001-02	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	

Labeler - FLYGIENE LLC (117528741)

Establishment

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

Revised: 1/2024

FLYGIENE LLC