

FLORANCE MORRIS ANTISEPTIC HAND SANITIZER- ethyl alcohol gel
Asimex International Llc

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.

Florance Morris body care ANTISPETIC HAND SANTITIZER

Drug Facts

Active ingredient

Ethyl alcohol 70%

Purpose

Antiseptic

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame

For external use only

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

- store between 15-30°C (59-86°F)

- avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

glycerin, hydroxyethylcellulose, triethanolamine, water

Questions?

+1-786-843-1308

You may also report serious side effects to this phone number.

Mon-Fri 9:00 AM - 5:00 PM

Florance Morris

body care

Distributed by: Asimex International LLC

9100 S Dadeland Blvd, Ste 912 Miami, FL, 33156

COUNTRY OF ORIGIN: MEXICO

Packaging

FLORANCE MORRIS ANTISEPTIC HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:766.12-170
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
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76612-170-06	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
2	NDC:76612-170-11	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
3	NDC:76612-170-12	125 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2020	
4	NDC:76612-170-25	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2020	
5	NDC:76612-170-50	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2020	
6	NDC:76612-170-10	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2020	
7	NDC:76612-170-37	4000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/23/2020	

Labeler - Asimex International Llc (025004798)

Establishment

Name	Address	ID/FEI	Business Operations
Grupo Asimex de México, S.A. de C.V.		812962512	manufacture(76612-170)

Revised: 6/2020

Asimex International Llc