FLORANCE MORRIS ANTISEPTIC HAND SANITIZER- alcohol gel ROLDAN INDUSTRIES

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 ANTISEPTIC Hand Sanitizer

Drug Facts

Active ingredient

Ethyl alcohol 70%

Purpose

Antiseptic

Use

- 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
- 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

Questions?

+1-786-843-1308

You may also report serious side effects to this phone number. Mon - Fri 9:00 AM - 5:00 PM

Distributed by: Roldan Industries

1500 E Tropicana Ave. Ste 154 Las Vegas NV 89119

COUNTRY OF ORIGIN: MEXICO

Packaging





Distributed by: Roldan Industries 1500 E Tropicana Ave. Ste 154 Las Vegas NV 89119 COUNTRY OF ORIGIN: MEXICO LOT NO. AND EXPIRY PRINTED ON BOTTLE



16.90 fl oz (500 mL)

Route of Administration

Florance Morris body care

Drug Facts Active ingredient Purpose Ethyl alcohol 70%. Antiseptic ■ 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 ■ 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 rendness develop ■ condition persists for more than 72 hours. Keep out of reach of children. If swallowed, get medical **Directions** ■ wet hands thoroughly with product and allow to dry without ■ 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 carbomer, EDTA, glycerol, polysorbate, 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 ANTISEPTIC HAND SANITIZER

TOPICAL

alcohol gel

Product information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79109-170

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)		
EDETIC ACID (UNII: 9G34HU7RV0)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
TROLAMINE (UNII: 903K93S3TK)		
WATER (UNII: 059QF0KO0R)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79109-170- 22	2 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	
2	NDC:79109-170- 06	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	
3	NDC:79109-170- 11	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	
4	NDC:79109-170- 12	125 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	
5	NDC:79109-170- 25	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	
6	NDC:79109-170- 50	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	
7	NDC:79109-170- 10	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	
8	NDC:79109-170- 37	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/18/2020		

Labeler - ROLDAN INDUSTRIES (117553465)

Revised: 8/2020 ROLDAN INDUSTRIES