

HAND SANITIZER- alcohol spray**Edith and Nancy 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.

Active Ingredient(s)

Alcohol 65% 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

purified water USP, rosemary extract, isopropyl myristate


Package Label - Principal Display Panel

059 mL NDC: 73373-114-01

developed and distributed in New York by
Edith and Nancy LLC
New York, NY 10019
edithnancy.com

bisoo[®]
hand sanitizer
rosemary
scented
2 FL OZ / 59 mL

consciously formulated



consciously manufactured

Drug Facts

Active Ingredient Ethyl Alcohol (65%)*	Purpose Antiseptic
Use For handwashing to decrease bacteria on hands	
Warnings For external use only. Flammable. Keep away from fire or flame. Do not use near eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if skin irritation develops.	
Keep out of reach of children If swallowed, get medical help or contact Poison Control Center right away.	
Directions Spray on palm, rub hands together. Supervise children under 6.	
Inactive Ingredients water, isopropyl myristate, rosemary oil	
Other Information Store at 20°-25°C (68°-77°F)	
Questions? Call 571-768-8430	

*denatured with rosemary oil

HAND SANITIZER

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73373-114
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ROSEMARY OIL (UNII: 8LGU7VM393)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73373-114-22	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final	part333A	04/13/2020	
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Labeler - Edith and Nancy LLC (117201647)

Establishment

Name	Address	ID/FEI	Business Operations
Edith and Nancy LLC		113680192	manufacture(73373-114)

Revised: 4/2020

Edith and Nancy LLC