

ROSE HAND SANITIZER- ethyl alcohol solution

Sutra Beauty Inc

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)

Ethyl Alcohol 75% v/v.

Purpose

Antiseptic

Inactive ingredients

Aloe Barbadosensis Leaf Extract, Aqua, Camellia Sinensis Leaf Oil, Carbomer, Rosmarinus Officinalis (Rosemary) Leaf Oil, Parfum.

Use

- Hand Sanitizer to help reduce bacteria that can potentially cause disease.
- For use when soap and water are not available.

Warnings

- For external use only.
- Flammable, keep away from fire or flame.

Do not use

- On children less than 2 months of age.
- On open skin wounds.

Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Irritation or rash occurs. These may be signs of a serious condition.

- If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

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).

Questions or Comments?

- Call 1-888-463-6332 Monday-Friday 9AM-5PM EST. FDA NDC Product Code: 76741-005-12

Package Label - Principal Display Panel

120 ml NDC: 76741-005-12

SOLEIL
Hand Sanitizer

4 OZ (120 ml)
MADE WITH ROSE
Helps Kill Germs & Bacteria Quickly
New Ultra Hygienic Formula

Drug Facts	
Active Ingredient Ethyl Alcohol 75% v/v	Purpose Antiseptic
Inactive Ingredients Aloe Barbadosis Leaf Extract, Aqua, Camellia Sinensis Leaf Oil, Carbomer, Rosmarinus Officinalis (Rosemary) Leaf Oil, Parfum.	
Use Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.	
Warnings For external use only. Flammable, keep away from fire or flame.	
Do not use On 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 (1-800-222-1222).	
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).	
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Distributed by:

SOLEIL
Van Nuys, CA 91406



Made in China
EXP: 08/2023

ROSE HAND SANITIZER

ethyl alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76741-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0KO0R)	
ROSEMARY OIL (UNII: 8LGU7VM393)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TEA LEAF OIL (UNII: VC855RRT77)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76741-005-12	120 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/14/2020	

Labeler - Sutra Beauty Inc (040228928)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Joy Claire Biological Technology Co.,Ltd		418209894	manufacture(76741-005)

Revised: 12/2020

Sutra Beauty Inc