

SURE WELL HAND SANITIZER (ETHANOL)- ethyl alcohol gel
COSNINE, 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 68%

Purpose

Antiseptic

Uses

Decrease bacteria on hands
Recommended for repeated use.

Warnings

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

When using this product

avoid contact with eyes.
if contact occurs, rinse thoroughly with water

Stop use and ask a doctor

if irritation and redness develop or increase.

Keep out of reach of children

if swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply a small amount onto hands and rub briskly until dry.
- Supervise children in the use of this product.

Other information

- Read the directions and warnings before use.
- Do not use for other purposes.
- Store at 1-30°C (33.8-86°F).

Inactive ingredients

Water, Glycerin, Carbomer, Triethanolamine

Package Label - Principal Display Panel

500 mL NDC: 73330-0016-1



SURE WELL HAND SANITIZER (ETHANOL)

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73330-0016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.68 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73330-0016-1	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - COSNINE, Inc. (694607163)**Establishment**

Name	Address	ID/FEI	Business Operations
COSNINE, INC.		694607163	manufacture(73330-0016)

Revised: 6/2020

COSNINE, Inc.