HAND CLEAN PLUS 100 (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 waterr

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 1-30oC (33.8-86oF).

Inactive ingredients

Water, Glycerin, Carbomer, Triethanolamine

Package Label - Principal Display Panel

500 mL NDC: 73330-0010-1





250 mL NDC: 73330-0010-2



100 mL NDC: 73330-0010-3







HAND CLEAN PLUS 100 (ETHANOL)

ethyl alcohol gel

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:73330-0010

Route of Administration TOPICAL

Active Ingredient/Active Moiety

TROLAMINE (UNII: 9O3K93S3TK)

Ingredient Name Basis of Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)
ALCOHOL (UNII: 3K9958 V90M) ALCOHOL 0.68 mL in 1 mL

Inactive Ingredients Ingredient Name Strength GLYCERIN (UNII: PDC6A3C0OX) CARBOMER HO MO PO LYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) WATER (UNII: 059QF0KOOR)

Packaging						
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:73330-0010- 1	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020		

2	NDC:73330-0010- 2	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020				
3 NDC:73330-0010- 3 100 mL in 1 TUBE; Type 0: Not a Combination Product 03/30		03/30/2020					
Marketing Information							
	Marketing Categ	ory Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			

03/30/2020

Labeler - COSNINE, Inc. (694607163)

OTC monograph not final part333A

Establishment						
Name	Address	ID/FEI	Business Operations			
COSNINE, Inc.		694607163	manufacture(73330-0010)			

Revised: 4/2020 COSNINE, Inc.