OUSTANE HAND SANITIZER- alcohol gel Cadence Keen Innovations, 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.

O'ustane Hand Sanitizer

Drug Facts

Active Ingredient

Ethyl Alcohol 75%

Purpose

Antiseptic

Uses

Hand washing to reduce bacteria on skin, suitable when water is unavailable

Warnings

External Use only

Flammable, keep away from fire or flame

When using this product

Avoid contact with eyes, rinse thoroughly with water if contact occurs

Stop using and ask a doctor if

Skin irritation or redness develop or increase

Keep out of reach of children

If swallowed, get medical attention or contact a Poison Control Center right away.

Directions

- Pour suitable enough product in your palm and rub together until dry.
- Children under 8 years of age should be used under supervision.

Inactive Ingredients

Water, Parfum(fragance), Propanediol, Polysorbate 20, Glycerin

Other Information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Package Labeling: 50ml



Hand Sanitizer

*Kills 99.9% of germs

1.69 fl oz (50ml)

O'ustane

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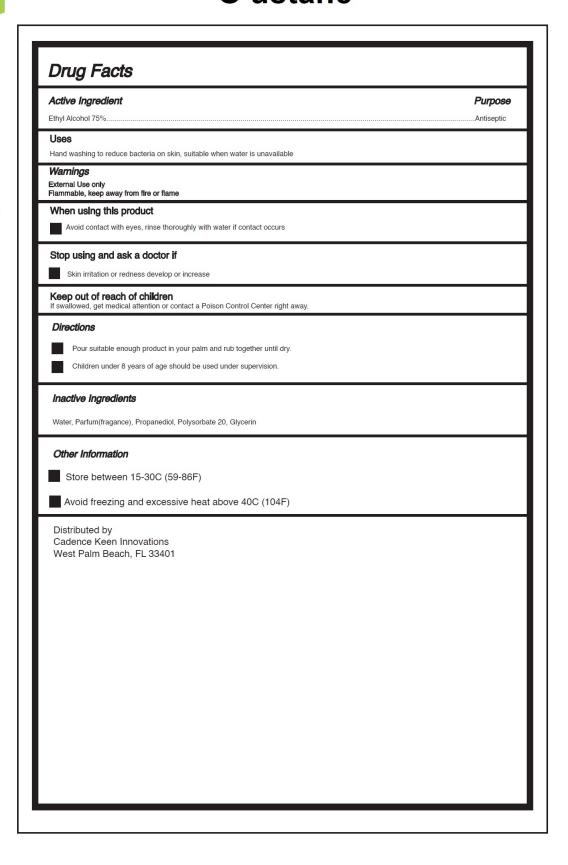


Hand Sanitizer

*Kills 99.9% of germs

16.907 fl oz (500ml)

O'ustane





Hand Sanitizer

*Kills 99.9% of germs

1 US gallon

3.785 L

O'ustane

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OUSTANE HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79128-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII: 3K9958 V90M)	ALCOHOL	0.75 mL in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
PROPANEDIOL (UNII: 5965N8W85T)			
POLYSORBATE 20 (UNII: 7T1F30V5YH)			
GLYCERIN (UNII: PDC6A3C0OX)			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79128-000-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/22/2020	
2	NDC:79128-000-16	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/22/2020	
3	NDC:79128-000-37	3785 mL in 1 DRUM; Type 0: Not a Combination Product	06/22/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/22/2020	

Labeler - Cadence Keen Innovations, Inc. (020785510)

Revised: 6/2020 Cadence Keen Innovations, Inc.