ALLPURE HAND SANITIZER- alcohol gel YESILILGAZ KOZMETIK KIMYA INSAAT OTOMOTIV VE GIDA SANAYI TICARET LIMITED SIRKETI

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

Ethyl Alcohol 70% v/v.

Purpose

Antiseptic

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 products 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.

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

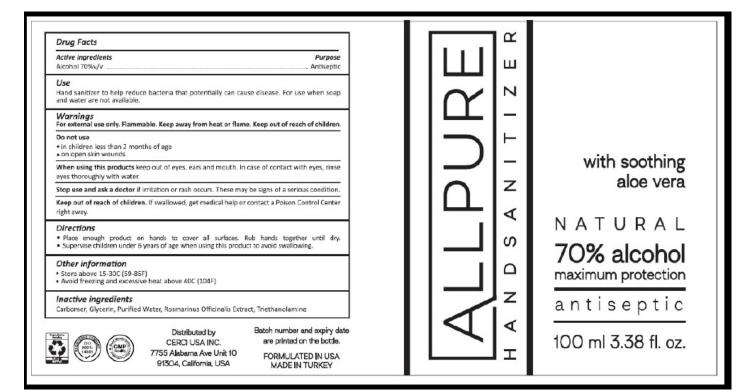
Store above 15·30C (59·86F)

Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Carbomer, Glycerin, Purified Water, Rosmarinus Officinalis Extract, Triethanolamine

Product label



ALLPURE HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78575-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)		
TROLAMINE (UNII: 9O3K93S3TK)		
ROSEMARY (UNII: IJ67X351P9)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78575-002- 01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/20/2020	

2	NDC:78575-002- 02	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/20/2020
3	NDC:78575-002- 03	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/20/2020
4	NDC:78575-002- 04	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/20/2020
5	NDC:78575-002- 05	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/20/2020
6	NDC:78575-002- 06	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/20/2020
7	NDC:78575-002- 07	5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/20/2020

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	07/20/2020		

$\textbf{Labeler-} \textbf{ YESILILGAZ KOZMETIK KIMYA INSAAT OTOMOTIV VE GIDA SANAYI TICARET LIMITED SIRKETI (355436838)$

Establishment			
Name	Address		Business Operations
YESILILGAZ KOZMETIK KIMYA INSAAT OTOMOTIV VE GIDA SANAYI TICARET LIMITED SIRKETI		355436838	manufacture(78575- 002)

Revised: 7/2020

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