### HAND SANITIZER- alcohol gel AKKIM YAPI KIMYASALLARI SANAYI VE TICARET ANONIM 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.

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### Akkim Hand Sanitizer Gel-100, 250, 500, 1000, 5000 ml

### **Active Ingredient(s)**

Alcohol 70% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

#### 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 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.

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#### **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

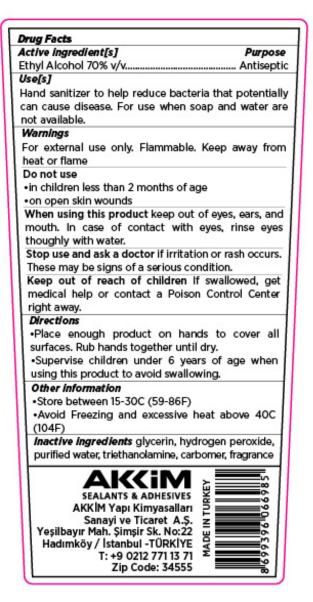
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## **Inactive ingredients**

glycerin, hydrogen peroxide, purified water, triethanolamine, carbomer, fragrance

## Package Label - Principal Display Panel 100 ml









Package Label, Principal Display Panel 500



Drug Facts		
Active ingredient[s]	Purpose	
Ethyl Alcohol 70% v/v	Antiseptic	
Use[s]		
Hand sanitizer to help reduce bacteria that potentially		
can cause disease. For use when	soap and water are	
not available.		
Warnings		
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or flame		
Do not use		
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help or contact a Poison Control Center right away.		
Directions		
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Rub hands together until dry.		
•Supervise children under 6 years of age when using		
this product to avoid swallowing.		
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Inactive ingredients glycerin, hydrogen peroxide,		
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SEALANTS & ADHESIVES AKKİM Yapı Kimyasalları Sanayi ve Ticaret A.Ş. Yeşilbayır Mah. Şimşir Sk. No:22 Hadımköy / İstanbul -TÜRKİYE T: +9 0212 771 13 71 Zip Code: 34555	MADE IN TURKEY  (699396-1067050	

Package Label, Principal Display Panel 1000 ml



#### Drug Facts

#### Active ingredient[s]

Purpose

Ethyl Alcohol 70% v/v..... Antiseptic

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Zip Code: 34555



Package Label, Principal Display Panel 5000 ml



G E L

No Rinse

**Fight Against** Germs

> Fresh Scent

1.32 GALLON (5 L)

 rua	100

Active ingredient[s] Purpose Ethyl Alcohol 70% v/v...... Antiseptic

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### **HAND SANITIZER**

alcohol gel

### **Product Information**

HUMAN OTC DRUG NDC:79886-002 **Product Type** Item Code (Source)

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			
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)				
TROLAMINE (UNII: 903K93S3TK)				
GLYCERIN (UNII: PDC6A3C0OX)				
HYDROGEN PEROXIDE (UNII: BBX060AN9V)				
WATER (UNII: 059QF0KO0R)				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:79886- 002-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2020		
2	NDC:79886- 002-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2020		
3	NDC:79886- 002-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2020		
4	NDC:79886- 002-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2020		
5	NDC:79886- 002-50	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2020		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/20/2020	

# **Labeler -** AKKIM YAPI KIMYASALLARI SANAYI VE TICARET ANONIM SIRKETI (366467348)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
AKKIM YAPI KIMYASALLARI SANAYI VE TICARET ANONIM SIRKETI		366467348	manufacture(79886-002) , pack(79886-002) , label(79886-002)

Revised: 12/2021 AKKIM YAPI KIMYASALLARI SANAYI VE TICARET ANONIM SIRKETI