

**RFL ANTISEPTIC HAND SANITIZER- alcohol liquid**  
**RFL AKVARYUM SISTEMLERİ SANAYİ VE TİCARET LİMİTED SİRKETİ**

*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.*

-----

**RFL ANTISEPTIC HAND SANITIZER**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (78,5%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol
- c. Aloe vera leaf juice
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

**Active Ingredient(s)**

Alcohol 78,5% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

for hand washing to decrease bacteria on the skin.

**Warnings**

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

**Do not use**

- in the eyes.

Stop use and ask a doctor if

-irritation and redness develop.

-condition persists for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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**

- Wet hands thoroughly with product and allow to dry without wiping.

### **Other information**

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

### **Inactive ingredients**

aloe vera leaf juice, deionized water, glycerin.

### **Package Label - Principal Display Panel**

250 mL NDC: 86807-001-01

# RFL®



Aloe Vera

## ANTISEPTIC HAND SANITIZER 78.5% ETHYL ALCOHOL

HAND DISINFECTION

Kills germs

### 8.5 fl oz (250 mL)

### Drug Facts

#### Active ingredient

Ethyl alcohol 78.5%

#### Purpose

Antiseptic

#### Use

■ for hand washing to decrease bacteria on the skin.

#### Warnings

For external use only.

Flammable, keep away from fire or flame.

Do not use in the eyes

Stop use and ask a doctor if

■ irritation and redness develop

■ condition persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison

Control Center right away.

#### Directions

■ Wet hands thoroughly with product and allow to dry without wiping.

#### Inactive ingredients

aloe vera leaf juice, deionized water, glycerin.

Rfl Akvaryum Sistemleri San. Ve Tic. Ltd. Sti.  
Handimkoy Mah. Turgut Reis Cad. No: 29/4  
Arnavutkoy, Istanbul  
Turkey

Made in Turkey

In the case of adverse event, contact  
803-591-9500.

Has fast effect. Dries quickly without leaving  
a sticky residue feeling in your hand. No  
need to rinse. Can be directly applied to  
hands. Does not contain any coloring agents  
or perfume.



## RFL ANTISEPTIC HAND SANITIZER

alcohol liquid

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:86807-001

Route of Administration

TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	78.5 mL in 100 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)				
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)				
<b>WATER</b> (UNII: 059QF0KO0R)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:86807-001-01	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final		part333A	03/30/2020	

**Labeler** - RFL AKVARYUM SISTEMLERI SANAYI VE TICARET LIMITED SIRKETI (505257103)

**Registrant** - RFL AKVARYUM SISTEMLERI SANAYI VE TICARET LIMITED SIRKETI (505257103)

## Establishment

Name	Address	ID/FEI	Business Operations
RFL AKVARYUM SISTEMLERI SANAYI VE TICARET LIMITED SIRKETI		505257103	manufacture(86807-001)

Revised: 1/2022

RFL AKVARYUM SISTEMLERI SANAYI VE TICARET LIMITED SIRKETI