

## **HAND SANITIZER- alcohol liquid**

**98 Leaf 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.*

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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) (80%, 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 (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- 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 80% 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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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 between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

### Inactive ingredients

glycerin, hydrogen peroxide, purified water USP


### Package Label - Principal Display Panel



\*Conforms to WHO, FDA, CDC and EN12791 guidance for COVID19


Alcohol Antiseptic 80%  
Topical Solution  
Hand Sanitizer  
Non-sterile Solution

Drug Facts	
<b>Active Ingredient(s)</b>	<b>Purpose:</b>
Ethyl Alcohol 75%.....	Antiseptic
<b>Use(s)</b>	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable, keep away from heat or flame.	
<b>Do not use</b>	
•On children less than 2 months of age •On open skin wounds	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact the Poison Control Center right away.	
<b>Directions</b>	
Place enough product on hands to cover entire surface. Rub hands together until dry.	
<b>Other information</b>	
•Store at room temperature 15-30°C(59-86°F) •Avoid freezing and excessive heat above 40°C(104°F)	
<b>Inactive Ingredients</b>	
Deionized Water, Glycerin, Hydrogen Peroxide	




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\*\*\* Made in USA \*\*\*





The Principal Display Panel of the Hand Sanitizer Gel packaging features a blue background with water droplets. At the top is the ameriguardRx logo. The product name "hand sanitizer gel+" is prominently displayed in large, bold, blue letters. Below the name, it says "FRAGRANCE FREE". At the bottom, a dark blue banner states "99.9% EFFECTIVE AGAINST GERMS". The volume "6.76 fl oz (200mL)" is printed at the very bottom.

000 mL NDC: 00000-000-00



\*Conforms to WHO, FDA, CDC and  
EN12791 guidance for COVID19

Alcohol Antiseptic 80%  
Topical Solution  
Hand Sanitizer  
Non-sterile Solution

## Drug Facts

**Active Ingredient(s)**      **Purpose:**  
Ethyl Alcohol 65%..... Antiseptic

### Use(s)

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

- On children less than 2 months of age
- On open skin wounds

**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 the Poison Control Center right away.

### Directions

Place enough product on hands to cover entire surface. Rub hands together until dry.

### Other information

- Store at room temperature 15-30°C(59-86°F)
- Avoid freezing and excessive heat above 40°C(104°F)

**Inactive Ingredients**  
Purified Water USP



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# hand sanitizer spray+

FRAGRANCE FREE

99.9% EFFECTIVE AGAINST GERMS

6.76 fl oz (200mL)

## HAND SANITIZER

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74727-000
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Product Characteristics				
Color			Score	
Shape			Size	
Flavor			Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74727-000-00	500000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2020	





## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/15/2020	

**Labeler** - 98 Leaf Inc (128561809)

**Registrant** - 98 Leaf Inc (128561809)

## Establishment

Name	Address	ID/FEI	Business Operations
98 Leaf Inc		128561809	manufacture(74727-000)

Revised: 4/2020

98 Leaf Inc