

**AQUAFIRE- alcohol gel**  
**SHERLEKAR AIRCARE PRIVATE LIMITED**

*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 70% v/v. Purpose: Antimicrobial

**Purpose**

Antimicrobial, Hand Sanitizer

**Use**

Hand sanitizer to help reduce bacteria on hands. 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

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 below 110F (43C)

**Inactive ingredients**

Water (Aqua), Isopropyl Alcohol, Glycerin, Tocopheryl Acetate, Acrylates / c-10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Extract, Triethanolamine

**Package Label - Principal Display Panel**

5 L NDC: 78931-001-01



<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Ethyl Alcohol 70% v/v.....	Antimicrobial
<b>Uses:</b> Hand sanitizer to help reduce bacteria on hands.	
<b>Warnings: For external use only. Flammable</b>	
Do not use ■ on 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.	
Keep out of reach of children. If swallowed, get medical help, or contact a Poison Control Center right away.	
<b>Directions:</b> ■ Place enough product in your palm to cover hands. Rub hands together until dry. ■ Supervise children under 6 years of age when using this product to avoid swallowing.	
<b>Other information:</b> Store below 110F (43C)	
<b>Inactive Ingredients:</b> Water (Aqua), Isopropyl Alcohol, Glycerin, Tocopheryl Acetate, Acrylates / c-10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Extract, Triethanolamine	
MANUFACTURED BY: SHERLEKAR AIRCARE PVT LTD., MANGALORE, INDIA 575008   NDC # 78931-001-01	

## AQUAFIRE

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78931-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 L in 100 L

### Inactive Ingredients

Ingredient Name	Strength
CARBOMER 980 (UNII: 4Q93RCW27E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

TROLAMINE (UNII: 9O3K93S3TK)

GLYCERIN (UNII: PDC6A3C0OX)

ISOPROPYL ALCOHOL (UNII: ND2M416302)

WATER (UNII: 059QF0K00R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78931-001-01	5 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - SHERLEKAR AIRCARE PRIVATE LIMITED (861721920)

Revised: 6/2020

SHERLEKAR AIRCARE PRIVATE LIMITED