

AQUAFIRE- alcohol liquid
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.

Liquid

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.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antimicrobial

Purpose

Antimicrobial, Hand Sanitizer

Use

Hand sanitizer to help reduce bacteria on hands.

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, Aloe Barbadensis Extract, Triethanolamine

Package Label - Principal Display Panel

5 L NDC: 78931-002-01

AQUAFIRE™



**HAND
SANITIZER
Liquid**

70% Alcohol
with Aloe Vera
5 Litre

Drug Facts	
Active Ingredient Ethyl Alcohol 70% v/v.....	Purpose Antimicrobial
Uses: Hand sanitizer to help reduce bacteria on hands.	
Warnings: For external use only. Flammable	
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.	
Directions: ■ 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.	
Other information: Store below 110F (43C)	
Inactive Ingredients: Water (Aqua), Isopropyl Alcohol, Glycerin, Aloe Barbadensis Extract, Triethanolamine	

MANUFACTURED BY: SHERLEKAR AIRCARE PVT LTD.,
MANGALORE, INDIA 575008 | NDC # 78931-002-01

AQUAFIRE

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78931-002
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
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78931-002-01	5000 mL 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)**Establishment**

Name	Address	ID/FEI	Business Operations
SHERLEKAR AIRCARE PRIVATE LIMITED		861721920	manufacture(78931-002)

Revised: 7/2020

SHERLEKAR AIRCARE PRIVATE LIMITED