# AQUALABS ANTISEPTIC HAND SANITIZER- ethyl alcohol gel Aquatonale FZC

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.

-----

#### AQUALABS ANTISEPTIC HAND SANITIZER GEL

#### **Drug Facts**

#### Active ingredient

Ethyl Alcohol 72% v/v

#### **Purpose**

**Antiseptic** 

#### Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

### Warnings

### Flammable, keep away from fire / flame. For external use only

#### Do not use

- in children less than 2 months of age
- on open skin wounds

**When using this product** • do not get into eyes. In case of contact, rinse eyes thoroughly with water

### 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
- supervise children under 6 years of age when using this product to avoid swallowing

#### Other information

- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above 40°C (104°F)

### Inactive ingredients

water, glycerin, carbomer, fragrance, triethanolamine, tocopheryl acetate.

### Questions?

+ 971 6 557 1415

You may also report serious side effects to this phone number.

Sat-Thur 9:00 AM - 6:00 PM

#### KILLS 99.9% OF GERMS

With Moisturizers & Vitamin E

#### MADE IN U.A.E.

www.aq-private-label.com

sales@aquatonale.ae

sales@aquatonale-fze.com

### **AQUATONALE GROUP**

Imitation of Graphics/Pack Design is a punishable offence.

#### Manufactured by:

Aquatonale FZC, P6-38, SAIF Zone, Sharjah.

**United Arab Emirates** 

### **Packaging**



### **Drug Facts**

Active ingredient Purpose Ethyl Alcohol 72% v/v. .Antiseptic

#### Uses

- hand sanitizer to decrease bacteria on the skin
  • recommended for repeated use
- for use when soap and water are not available

### Warnings

Flammable, keep away from fire / flame. For external use only

- in children less than 2 months of age
   on open skin wounds

When using this product . do not get into eyes. In case of contact, rinse eyes thoroughly with water

#### 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
- supervise children under 6 years of age when using this product to avoid swallowing

#### Other information

- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above 40°C (104°F)

#### Drug Facts (continued)

Inactive ingredients water, glycerin, carbomer, fragrance, triethanolamine, tocopheryl acetate.

#### Questions? +971 6 557 1415

You may also report serious side effects to this phone number. Sat Thru 9:00 AM - 6:00 PM

#### MADE IN U.A.E.

www.aq-private-label.com sales@aquatonale.ae sales@aguatonale-fze.com







Manufactured by:

Aquatonale FZC, P6-38, SAIF Zone, Sharjah. United Arab Emirates

### AQUALABS ANTISEPTIC HAND SANITIZER

ethyl alcohol gel

#### **Product Information**

**Item Code (Source) Product Type** HUMAN OTC DRUG NDC:80953-894

**Route of Administration TOPICAL** 

### **Active Ingredient/Active Moiety**

**Basis of Strength** Strength **Ingredient Name** ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII: 3K9958V90M) ALCOHOL 72 mL in 100 mL

| Inactive Ingredients     |                 |          |  |
|--------------------------|-----------------|----------|--|
|                          | Ingredient Name | Strength |  |
| WATER (UNII: 059QF0KO0R) |                 |          |  |

| GLYCERIN (UNII: PDC6A3C0OX)                               |  |
|---|--|
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) |  |
| TROLAMINE (UNII: 903K93S3TK)                              |  |
| .ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)               |  |

| Packaging                 |  |                         |                       |  |
|---------------------------|--|-------------------------|-----------------------|--|
| # Item Cod                | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |  |
| <b>1</b> NDC:80953-894-10 | 295.7 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 11/26/2020              |                       |  |

| Marketing Information   |   |                         |                       |  |  |
|-------------------------|---|-------------------------|-----------------------|--|--|
| Marketing<br>Category   | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |  |
| OTC monograph not final | part333A                                    | 11/26/2020              |                       |  |  |
| final                   | pa. 1555, 1                                 | 11,20,2020              |                       |  |  |

## Labeler - Aquatonale FZC (851675237)

| Establishment  |         |           |                        |  |
|----------------|---------|-----------|------------------------|--|
| Name           | Address | ID/FEI    | Business Operations    |  |
| Aquatonale FZC |         | 851675237 | manufacture(80953-894) |  |

Revised: 11/2022 Aquatonale FZC