

**HAND SANITIZER- hand sanitizer gel**  
**Xiamen Afgamarine Biotechnology Co., Ltd.**

*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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**Afgamarine, Hand Sanitizer, Ethanol 75%, Gel**

**Active Ingredient(s)**

Ethyl Alcohol 75% v/v. Purpose: Antimicrobial

**Purpose**

Antimicrobial.

**Use**

Recommended uses:

External use to help reduce bacteria on the skin.

**Warnings**

Cautions and Warning:

DANGER! Flammable warning. Keep away from open flame and sources of heat.  
For external use only.

**Do not use**

Contraindications:

Do not use on children/infants less than 2 years of age (unless directed by a doctor/physician/health care practitioner/health care provider/health care profession).

When using this product avoid contact with eyes.

Stop use and ask/consult a doctor/physician/health care practitioner/health care provider/health care profession if irritation develops and lasts.

Keep out of reach of children. If swallowed, call a poison control center or get medical help right away.

**Directions**

Supervise children when they use this product. For occasional and personal cosmetic use. Rub thoroughly into hands for at least 30 seconds. Allow to dry.

**Other information**

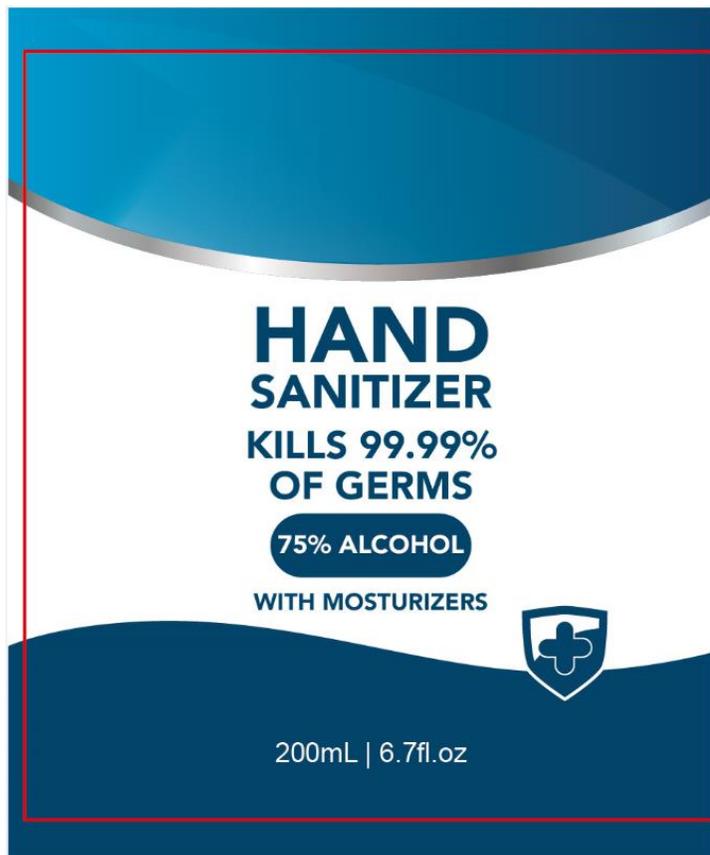
Security Package: Security feature is self-evident.

Waste disposal: The disposal of this product and container shall be in accordance with local/national regulations.

## Inactive ingredients

Aqua, Glycerin, Carbomer, Parfum, Triethanolamine.

## Package Label - Principal Display Panel



**HAND SANITIZER**  
KILLS 99.99% OF GERMS  
75% ALCOHOL  
WITH MOSTURIZERS

200mL | 6.7fl.oz

**HAND SANITIZER**

**Active Ingredient:**  
Alcohol (Ethyl alcohol, Ethanol) 75%

**Recommended Uses:**  
External use to help reduce bacteria on the skin

**Contraindications:**  
Do not use on children/infants less than 2 years of age (unless directed by a doctor/physician/health care practitioner/ health care provider/ health care profession).

**Directions:**  
Supervise children when they use this product. For occasional and personal domestic use. Rub thoroughly into hands for at least 30 seconds. Allow to dry.

**Cautions and Warning:**  
**DANGER!** Flammable warning. Keep away from open flame and sources of heat. For external use only. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Stop use and ask/consult a doctor/physician/health care practitioner/ health care provider/ health care professional if irritation develops. and lasts When using this product avoid contact with eyes.

**Inactive Ingredients:**  
Aqua, Glycerin, Carbomer, Parfum, Triethanolamine. This product does not contain mercury.

**EXP:**  
**Security Package:** Security feature is self-evident.  
**Waste disposal:** The disposal of this product and container shall be in accordance with local/national regulations.

MANUFACTURED BY XIAMEN AFGAMARINE BIOTECHNOLOGY CO., LTD.  
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MADE IN CHINA



## HAND SANITIZER

hand sanitizer gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:776 07-100
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	75 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
WATER (UNII: 059QF0K00R)	
DICHRISTACHYS CINEREA WHOLE (UNII: N27D64ME6P)	

TROLAMINE (UNII: 9O3K93S3TK)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77607-100-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
2	NDC:77607-100-03	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
3	NDC:77607-100-05	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
4	NDC:77607-100-08	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
5	NDC:77607-100-09	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
6	NDC:77607-100-12	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
7	NDC:77607-100-15	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
8	NDC:77607-100-19	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/19/2020	

**Labeler** - Xiamen Afgamarine Biotechnology Co., Ltd. (420485152)

**Registrant** - A03 Lab of BTS (548009541)

### Establishment

Name	Address	ID/FEI	Business Operations
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(77607-100) , label(77607-100)

Revised: 5/2020

Xiamen Afgamarine Biotechnology Co., Ltd.