

## **HAND SANITIZER- alcohol gel**

### **Griffo Distillery**

*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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### **Active Ingredient(s)**

Alcohol 70% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease.

### **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

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

### **Inactive ingredients**


Water, Methylcellulose

## Questions:

Griffo Distillery LLC, Petaluma, CA 94954

(707) 879-8755 info@GriffoDistillery.com

## Package Label - Principal Display Panel



# HAND SANITIZER


Alcohol Antiseptic 70%  
Topical Solution

**LIQUID**

3785ml (1 GAL)

### Drug Facts

Active Ingredients	Purpose
Ethyl Alcohol 70%	Antiseptic
<b>Purpose:</b> Antiseptic, Hand Sanitizer	
<b>Uses:</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease.	
<b>Warnings:</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b> in children less than 2 months of age on open skin wounds	
<b>When using this product:</b> Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse 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.	
<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 a Poison Control Center right away.	
<b>Directions:</b> 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.	
<b>Other Information:</b> Store between 15 - 30 C (59 - 86 F) Avoid freezing and excessive heat above 40C (104 F)	
<b>Inactive Ingredients:</b> Water, Methylcellulose	
<b>Questions?</b> Griffo Distillery, LLC, Petaluma, CA 94954 707-879-8755 info@griffodistillery.com	



7 37212 00832 5 NDC:75196-001-11

3785 ml NDC: 75196-001-11

## HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75196-001
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	
METHYLCELLULOSE (4000 CPS) (UNII: MRJ667KA5E)			1.3 mL in 100 mL	
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75196-001-11	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/14/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final		part333A	04/14/2020	

**Labeler** - Griffo Distillery (079801679)

**Registrant** - Griffo Distillery (079801679)

## Establishment

Name	Address	ID/FEI	Business Operations
Griffo Distillery		079801679	manufacture(75196-001)

Revised: 4/2020

Griffo Distillery