

**HAND SANITIZER- alcohol gel**  
**OXYGEL ALOE VERA- alcohol gel**  
**Matilde Gómez López**

*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. For use when soap and water are not available.

**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

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.

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.

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

**Inactive ingredients**

NDC 78084-001: purified water USP, glycerin, carbomer, triethanolamine.

NDC 78084-002: purified water USP, glycerin, carbomer, triethanolamine, aloe vera.

### Package Label - Principal Display Panel

500 mL NDC:78084-001-01

The Principal Display Panel features the brand name "OXYGEL" in large blue letters with a red cross icon to the left, and "212" in red to the right. Below this is a shield-shaped logo with "ANTISEPTIC" at the top, a red cross, and "Of Germs and Bacteria\*" below. To the right of the shield is a red banner with "ANTI-BACTERIAL" and "70% ALCOHOL" in white. At the bottom is a blue banner with "HAND SANITIZER" in white, and "16.9 FL OZ (500 ml)" in black below it.

1000 mL NDC: 78084-001-02

The back panel features a red banner at the top with "HAND SANITIZER" in white. Below is a "DRUG FACTS" table with sections for Active Ingredient, Uses, Warnings, Directions, Other Information, and Inactive ingredients. At the bottom, there is a red banner with "OXYGEL 212" and a blue banner with distributor information: "DISTRIBUTED BY: FX Imports: La Habra, CA 90631 Phone: 562-536-7400".

DRUG FACTS	
<b>Active ingredient</b>	<b>Purpose</b>
Ethyl alcohol 70% v/v	Antimicrobial
<b>Uses</b>	
· Hand sanitizer to help reduce bacteria on the skin that could cause disease.	
· Recommended for repeated use.	
<b>Warnings:</b>	
· Flammable. Keep away from fire or flame.	
· For external use only.	
· When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.	
· Stop use and ask a doctor if irritation or rash appears and lasts.	
· 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 thoroughly cover your hands.	
· Rub hands together briskly until dry.	
· Children under 6 years of age should be supervised by an adult when used OXYGEL 212.	
<b>Other Information</b>	
· Do not store above 110 °F (43 °C).	
· May discolor certain fabrics or surfaces.	
<b>Inactive ingredients</b>	
· Water, carbomer, triethanolamine and glycerin.	

\* Antiseptic of most common germs that may cause illness.

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# OXYGEL<sup>+</sup> 212



**ANTI-BACTERIAL  
70% ALCOHOL**

**HAND SANITIZER**

**33.8 FL OZ (1L)**

200000 mL NDC: 78084-001-03

## HAND SANITIZER

### DRUG FACTS

Active ingredient	Purpose
Ethyl alcohol 70% v/v	Antimicrobial

#### Uses

- Hand sanitizer to help reduce bacteria on the skin that could cause disease.
- Recommended for repeated use.

#### Warnings:

- Flammable. Keep away from fire or flame.
- For external use only.
- When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.
- Stop use and ask a doctor if irritation or rash appears and lasts.
- 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 thoroughly cover your hands.
- Rub hands together briskly until dry.
- Children under 6 years of age should be supervised by an adult when using OXYGEL 212.

#### Other Information

- Do not store above 110° F (43° C).
- May discolor certain fabrics or surfaces.

#### Inactive ingredients

- Water, carbomer, triethanolamine and glycerin.

\* Antiseptic of most common germs that may cause illness.



**OXYGEL<sup>+</sup> 212**

DISTRIBUTED BY: FX Imports: La Habra, CA 90631  
Phone: 562-536-7400

# OXYGEL 212



**ANTI-BACTERIAL  
70% ALCOHOL**

**HAND SANITIZER**

**6762.8 FL OZ (200 L)**

## HAND SANITIZER

### DRUG FACTS

Active ingredient	Purpose
Ethyl alcohol 70% w/v	Antimicrobial
<b>Uses</b>	
<ul style="list-style-type: none"> <li>Hand sanitizer to help reduce bacteria on the skin that could cause disease.</li> <li>Recommended for repeated use.</li> </ul>	
<b>Warnings:</b>	
<ul style="list-style-type: none"> <li>Flammable. Keep away from fire or flame.</li> <li>For external use only.</li> <li>When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.</li> <li>Stop use and ask a doctor if irritation or rash appears and lasts.</li> <li>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</li> </ul>	
<b>Directions:</b>	
<ul style="list-style-type: none"> <li>Place enough product in your palm thoroughly cover your hands.</li> <li>Rub hands together briskly until dry.</li> <li>Children under 6 years of age should be supervised by an adult when using OXYGEL 212.</li> </ul>	
<b>Other Information</b>	
<ul style="list-style-type: none"> <li>Do not store above 110 ° F (43 ° C).</li> <li>May discolor certain fabrics or surfaces.</li> </ul>	
<b>Inactive ingredients</b>	
<ul style="list-style-type: none"> <li>Water, carbomer, triethanolamine and glycerin.</li> </ul>	

\* Kills of most common germs that may cause illness.



**OXYGEL 212**

DISTRIBUTED BY: FX Imports: La Habra, CA 90631  
Phone: 562-536-7400

500 mL NDC:78084-002-01

**OXYGEL**  
212  
WITH ALOE VERA  
TAKE CARE AND REGENERATE YOUR SKIN

**ANTISEPTIC**  
Of Germs and Bacteria\*

**ANTI-BACTERIAL**  
70% ALCOHOL

**HAND SANITIZER**

16.9 FL OZ (500 ml)

**HAND SANITIZER**

DRUG FACTS	
Active ingredient(s) Ethyl alcohol (70%)	Prevention Antimicrobial
<b>Uses</b> -For skin care to help reduce bacteria on the skin that can cause disease. -For removal of germs on skin.	
<b>Warnings:</b> -Flammable. Keep away from fire or flame. -For external use only. -When using this product, avoid use in or near flames. In case of contact, rinse with water thoroughly with water. -Keep away from children. If swallowed, get medical help or contact Poison Control Center right away.	
<b>Directions:</b> -Place enough product in your palm thoroughly to wet your hands. -Rub hands together thoroughly with dry palms. -Continue until your hands feel completely dry. -When using GONELLE.	
<b>Other Information</b> -Store at controlled room temperature (20°-25°C). -May contain parabens or carboxylates.	
<b>Contains ingredients</b> -Water, sodium lauryl ether sulfate, glycerin and alcohol extract.	

\*As a guide of use, always use the correct amount.

**OXYGEL**  
212

DISTRIBUTED BY: FX Imports, La Habra, CA 90631  
Phone: 562-536-3400

1000 mL NDC:78084-002-02

**OXYGEL**  
212  
WITH ALOE VERA  
TAKE CARE AND REGENERATE YOUR SKIN

**ANTISEPTIC**  
Of Germs and Bacteria

**ANTI-BACTERIAL**  
70% ALCOHOL

**HAND SANITIZER**  
33.8 FL OZ (1L)

**HAND SANITIZER**

DRUG FACTS	
<b>Active ingredient(s)</b> Ethyl alcohol (70%)	<b>Proprietary</b> Antibacterial
<b>Uses</b> -For skin to help reduce bacteria on the skin that can cause disease. -For removal of germs on skin.	
<b>Warnings:</b> -Flammable. Keep away from fire or flame. -Irritant to skin only.	
<b>Directions:</b> Dispense desired dose of gel to or over the areas in case of contact, rub on skin thoroughly with water.	
<b>Precautions:</b> -Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.	
<b>Other information:</b> -Store at room temperature (20°-25°C). -May contain trace amounts of parabens.	
<b>Contains ingredients:</b> -Ethyl alcohol, carbocyanine, glycerol and other preservatives.	

\*As little as one microorganism that may cause illness.

**OXYGEL**  
212

DISTRIBUTED BY: TX Imports, La Habra, CA 90631  
Phone: 562-536-3400

250 mL NDC:78084-002-03



## HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78084-001
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
CARBOMER 940 (UNII: 4Q93RCW27E)	1.8 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	6.7 mL in 100 mL
TRIETHANOLAMINE HYDRIOIDE (UNII: DT98IT03JK)	1.8 g in 100 mL
WATER (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78084-001-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78084-001-02	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78084-001-03	200000 mL in 1 DRUM; 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	

**OXYGEL ALOE VERA**

alcohol gel

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78084-002
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
CARBOMER 940 (UNII: 4Q93RCW27E)	3 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	5 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF POLYSACCHARIDES (UNII: W21O437517)	5 mL in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78084-002-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/2020	
2	NDC:78084-002-02	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/2020	
3	NDC:78084-002-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/2020	



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/22/2020	

**Labeler** - Matilde Gómez López (951577135)

**Registrant** - Matilde Gómez López (951577135)

## Establishment

Name	Address	ID/FEI	Business Operations
Matilde Gómez López		951577135	manufacture(78084-001, 78084-002) , pack(78084-001, 78084-002) , label(78084-001, 78084-002)

Revised: 7/2020

Matilde Gómez López