

## **HAND SANITIZER- ethyl alcohol gel**

**Organikisimo, S.A. de C:V.**

*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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**ORG-125ML LEMON-GEL NDC 79337-167-01**

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

Ethyl 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.

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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**

Water, Polyacrylic acid, glycerin, Triethanolamine, lemon Fragrance.

# Package Label - Principal Display Panel



125 ml NDC 79337-167-01

<b>Drug Facts</b>	
<b>Active ingredient</b> Ethyl Alcohol, 70% v/v	<b>Purpose</b> Antiseptic
<b>Use(s)</b> ■ Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<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 keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</b>	
<b>Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</b>	
<b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</b>	
<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 40 °C (104 °F)	
<b>Inactive ingredients</b> Water, Polyacrylic acid, Glycerin, Triethanolamine, Lemon fragrance.	
<b>Questions or comments?</b> +82 1 81 6055 5372 ■ feedback@grupodisa.com	

Manufactured by:  
Organisano, S.A. de C.V.,  
Av. Industria Biotecnológica  
#100, Parque Industrial  
Pescuaria, Pescuaria,  
Nuevo León, México.  
66590.  
Lot number and expiration  
date on container

PRODUCT OF MEXICO

## HAND SANITIZER

ethyl alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79337-167
<b>Route of Administration</b>	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
TROLAMINE (UNII: 9O3K93S3TK)	0.1 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.8 mL in 100 mL
WATER (UNII: 059QF0KO0R)	28.3 mL in 100 mL
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	0.6 mL in 100 mL
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	0.2 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79337-167-01	125 mL in 1 BOTTLE, DISPENSING; 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** - Organikisimo, S.A. de C.V. (951579669)

**Registrant** - Organikisimo, S.A. de C.V. (951579669)

**Establishment**

Name	Address	ID/FEI	Business Operations
Organikisimo, S.A. de C.V.		951579669	manufacture(79337-167)

Revised: 8/2020

Organikisimo, S.A. de C.V.