

## **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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**8.45 OZ (250ml)**

### **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**

Deionized Water, Polyacrylic, glycerin, Fragrance, Triethanoamine

**Package Label - Principal Display Panel**

250 ml NDC:79337-250-01



Manufactured by:  
Organikisimo, S.A. de C.V.,  
Av. Industria Siderúrgica  
#100, Parque Industrial  
Pesquería, Pesquería,  
Nuevo León, México.  
66650.

Distributed by:  
Organikisimo, S.A. de C.V.  
410 Nafta, Laredo, TX.  
78045.

**Drug Facts**

**Active ingredient Purpose**  
Ethyl Alcohol, 70% v/v .....Antiseptic

**Uses**

- Hand sanitizer, alcohol-based, used to kill bacteria in order to prevent diseases.
- Ready to be used, as often as needed.

**Warnings**

**For external use only**

Flammable. Keep away from fire or flame. Do not use near the eyes. In case of contact, rinse thoroughly with water. If irritation develops, discontinue use and ask doctor. Keep out of reach of children. If swallowed, get medical help or call a Poison Control Center immediately. ▶

**Drug facts** (continued)

**Directions**

- Place a small amount in your hands and rub together until dry.
- No rinsing required.

**Other information**

- Do not store above 104°F (40°C).
- Careful, may discolor certain surfaces or textiles.

**Inactive ingredients**

Deionized water, Polyacrylic acid, Glycerin, Fragrance, Triethanolamine.

**Questions or comments?**

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feedback@grupodyasa.com



PRODUCT OF MEXICO

Lot number and expiration date on container.

**HAND SANITIZER**

ethyl alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79337-250
<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)	0.3 mL in 100 mL
WATER (UNII: 059QF0K00R)	24.3 mL in 100 mL
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	4.9 mL in 100 mL
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.4 mL in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79337-250-01	250 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(79337-250)

Revised: 7/2020

Organikisimo, S.A. de C.V.