

## **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-500ML LAVENDER GEL NDC 79337-162-01**

### **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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### **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, lavender Fragrance.

Package Label - Principal Display Panel

500 ml NDC:79337-162-01 A

**PLUS DE SANTÉ**

**HAND SANITIZER**

**LAVENDER**

with Moisturizers

70% Alcohol

16.90 FL OZ (500ml)

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Ethyl Alcohol, 70% v/v	Antiseptic
<b>Use[s]</b>	
<ul style="list-style-type: none"> <li>Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</li> </ul>	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>In children less than 2 months of age</li> <li>On open skin wounds</li> </ul>	
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.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>Store between 15-30 °C (59-86 °F)</li> <li>Avoid freezing and excessive heat above 40 °C (104 °F)</li> </ul>	
<b>Inactive ingredients</b>	
Water, Polyacrylic acid, Glycerin, Triethanolamine, Lavender fragrance.	
<b>Questions or comments?</b>	
+52 1 81 8685 5372 ■ <a href="mailto:feedback@grupodyasa.com">feedback@grupodyasa.com</a>	

Manufactured by:  
Organikismo, S.A. de C.V., Av. Industria Siderúrgica #100, Parque Industrial Pequeña, Pequeña, Nuevo León, México. 69650.



PRODUCT OF MEXICO

<b>HAND SANITIZER</b>			
ethyl alcohol gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79337-162
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	
<b>Inactive Ingredients</b>			
Ingredient Name	Strength		

<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	0.1 mL in 100 mL
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	0.8 mL in 100 mL
<b>WATER</b> (UNII: 059QF0K00R)	28.3 mL in 100 mL
<b>POLYACRYLIC ACID (8000 MW)</b> (UNII: 73861X4K5F)	0.6 mL in 100 mL
<b>FRAGRANCE LAVENDER &amp; CHIA F-153480</b> (UNII: SXS9CO2TZK)	0.2 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79337-162-01	500 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	03/03/2020	

**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(79337-162)

Revised: 8/2020

Organikisimo, S.A. de C.V.