

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.

ORG-500ML LEMON-GEL NDC 79337-169-01 alto

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.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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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, lemon Fragrance.

Package Label - Principal Display Panel

500 ml NDC 79337-169-01

PLUS DE SANTÉ

HAND SANITIZER

LEMON

with Moisturizers

70% Alcohol

16.90 FL OZ (500ml)

Drug Facts	
Active ingredient	Purpose
Ethyl Alcohol, 70% v/v	Antiseptic
Use[s]	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> 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.	
Directions	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> Store between 15-30 °C (59-86 °F) Avoid freezing and excessive heat above 40 °C (104 °F) 	
Inactive ingredients	
Water, Polysacrylic acid, Glycerin, Triethanolamine, Lemon fragrance.	
Questions or comments?	
+52 1 81 8685 5372 ■ feedback@grupodyasa.com	

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



PRODUCT OF MEXICO

HAND SANITIZER			
ethyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79337-169
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	

TROLAMINE (UNII: 9O3K93S3TK)	0.1 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.8 mL in 100 mL
WATER (UNII: 059QF0K00R)	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:79337-169-01	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	03/30/2020	

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(79337-169)

Revised: 8/2020

Organikisimo, S.A. de C.V.