

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.

16.9 OZ (500ml) CAMPANA

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.

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

500 ml NDC:79337-500-01



HAND SANITIZER

with Moisturizers

 **70% Alcohol**

16.90 FL OZ (500ml)

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.

Directions

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

Other information

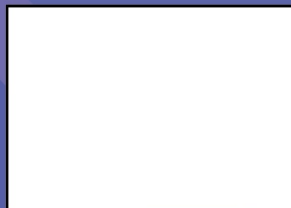
- Do not store above 104°F (40°C)
- Careful, may discolor certain surfaces or textiles

Inactive Ingredients

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

Questions or comments?

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Lot number and expiration date on container



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

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

PRODUCT OF MEXICO

HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79337-500
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
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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:79337-500-01	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(79337-500)

Revised: 7/2020

Organikisimo, S.A. de C.V.