

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.

4.22 OZ (125)

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

PLUS DE SANTÉ
HAND SANITIZER
 with Moisturizers
 70% Alcohol
 4.22 FL OZ (125ML)

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?
 +52 1 81 8885 5372
 feedback@grupodyasa.com

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.



Lot number and expiration date on container
 PRODUCT OF MEXICO



125 ml NDC:79337-125-01

HAND SANITIZER			
ethyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79337-125
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)	0.3 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			
		Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79337-125-01	60 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(79337-125)

Revised: 7/2020

Organikisimo, S.A. de C.V.