

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-250ML LEMON-GEL NDC 79337-168-01

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

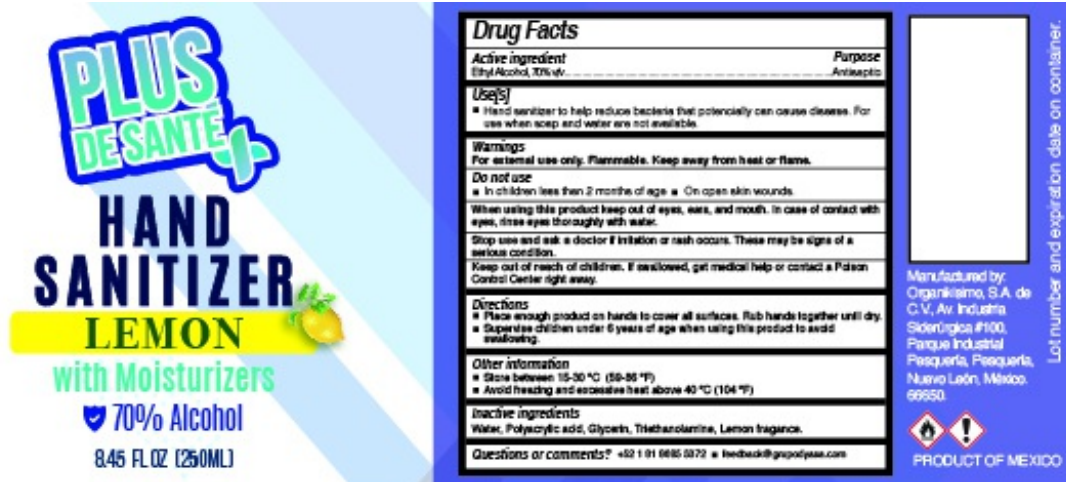
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Water, Polyacrylic acid, glycerin, Triethanolamine, lemon Fragrance.

Package Label - Principal Display Panel

250ml NDC 79337-168-01



HAND SANITIZER				
ethyl alcohol gel				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79337-168	
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: 059QF0KO0R)			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:79337-168-01	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(79337-168)

Revised: 8/2020

Organikisimo, S.A. de C.V.