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-galon LEMON-GEL NDC 79337-171-01

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.

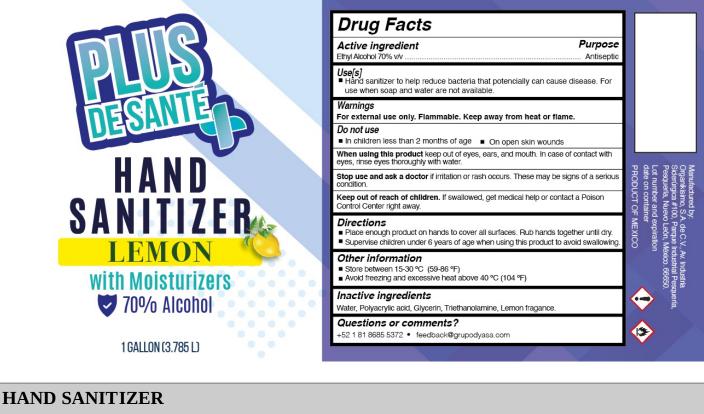
Other information

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

Inactive ingredients

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

Package Label - Principal Display Panel



ethyl alcohol gel

TOPICAL	em Code (Source)	NDC:79337-171	
Moiety			
•			
•			
ngredient Name			
Ingredient Name Basis of		h Strength	
) (ALCOHOL - UNII:3K9958V90M)	DL - UNII:3K9958V90M) ALCOHOL		
0		Strength	
0	0.1 ml	in 100 mL	
UNII: 903K93S3TK) 0.1 mL in 100 mL NII: PDC6A3C00X) 0.8 mL in 100 mL		L in 100 mL	
		28.3 mL in 100 mL	
LYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F) 0.6 mL in 100 mL			
W) (UNII: 73861X4K5F)	0.6 m	L in 100 mL	
	Ingredient Name ^{TK})	Ingredient Name 0.1 ml (K) 0.8 ml	

	3785 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Co Product	o mbinatio n 0 3/30/20 20				
Marketing Information						
Marketing Categ	ory Application Number or Monograph Cita	tion 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(79337-171)

Revised: 8/2020

Organikisimo, S.A. de C:V.