#### 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.

-----

#### 8.45 OZ (250ml)

#### **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, Polyacylic, glycerin, Fragrance, Triethanoamine

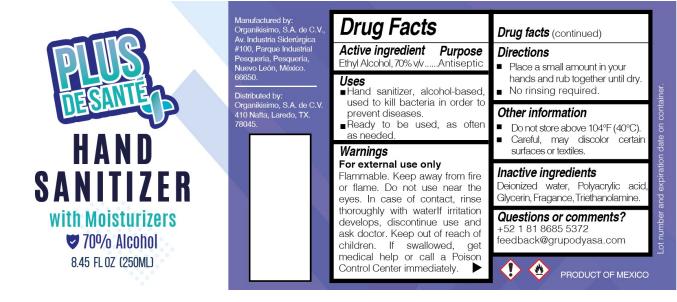
# Package Label - Principal Display Panel

250 ml NDC:79337-250-01

HAND SANITIZER

01

Product



etl	nyl alcohol gel						
P	roduct Inform	nation					
P	roduct T ype	HUMAN OTC DRUG Item Code (Source)		(Source)	NDC:79337-250		
R	oute of Administ	tration	TOPICAL				
A	ctive Ingredie	ent/Active Moi	ety				
Ingredient Name Basis of Stree						gth	Strength
A	LCOHOL (UNII: 3	K9958V90M) (ALC	OHOL - UNII:3K9958V90M)		ALCOHOL		$70\ mL$ in $100\ mL$
Iı	nactive Ingred	lients					
			Ingredient Name				Strength
TROLAMINE (UNII: 903K93S3TK)						0.1 mL in 100 mL	
GLYCERIN (UNII: PDC6A3C0OX)						0.3 mL in 100 mL	
WATER (UNII: 059QF0KO0R)						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	
P	ackaging						
#	Item Code		Package Description		Marketing St Date	art	Marketing End Date
1	NDC:79337-250-	250 mL in 1 BOTT	LE, DISPENSING; Type 0: Not a C	Combination	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	<b>Business Operations</b>
Organikisimo, S.A. de C:V.		951579669	manufacture(79337-250)

Revised: 7/2020

Organikisimo, S.A. de C:V.