TRADEMARK HAND SANITIZER- 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.

TRADEMARK HAND SANITIZER Alcohol 70%

Active Ingredient(s)

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic

Use

For sanitizing to help reduce bacteria on the skin that potentially can cause disease.

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.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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

Water, Carbomer, Glycerin, Triethanolamine, Tocopheryl Acetate (Vitamin E).

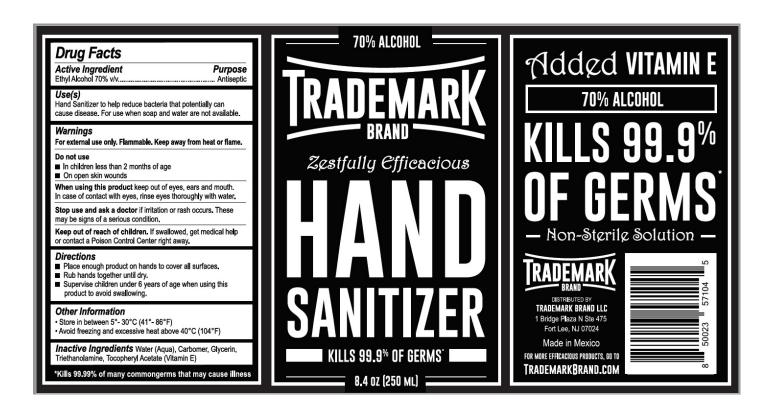
Package Label - TRADEMARK 59 ml NDC:79337-172-01

59 ml NDC:79337-172-01



Package Label - TRADEMARK 250 ml NDC:79337-172-02

250 ml NDC: 79337-172-02



Package Label - TRADEMARK 1000 ml NDC:79337-172-03

1000 ml NDC: 79337-172-03



Package Label - TRADEMARK 3785 ml NDC: 79337-172-04

3785 ml NDC: 79337-172-04



TRADEMARK HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79337-172	
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: 903K93S3TK)	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		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	0.15 mL in 100 mL		

ŀ	Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:79337-172- 01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/19/2020		
נו	NDC:79337-172-	250 ml in 1 ROTTI F. Type O. Not a Combination Product	11/10 /20 20		

4	02	230 IIIL III 1 DO I I LE, 19PE O. MOLA COMUNIAUON FIOUUCI	11/13/20/20	
3	NDC:79337-172- 03	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/19/2020	
4	NDC:79337-172- 04	3785 mL in 1 CONTAINER; Type 0: Not a Combination Product	11/19/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	11/19/2020		

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(79337-172)	

Revised: 11/2020 Organikisimo, S.A. de C:V.