

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

<p>Drug Facts</p> <table border="0"> <tr> <td>Active Ingredient</td> <td>Purpose</td> </tr> <tr> <td>Ethyl Alcohol 70% w/v.....</td> <td>Antiseptic</td> </tr> </table> <p>Use(s) For sanitizing to help reduce bacteria on the skin that potentially can cause disease.</p> <p>Warnings For external use only. Flammable. Keep away from heat or flame.</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ With children less than 2 months of age. ■ On open skin wounds. <p>When using this product keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p>Keep out of the reach of children unless under adult supervision. If swallowed, get medical help or contact a poison control center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> ■ 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. <p>Other Information Store in between 5°-30°C (41°-86°F) Avoid freezing and excessive heat above 40°C (104°F)</p> <p>Inactive Ingredients Water (Aqua), Carbomer, Glycerin, Triethanolamine, Tocopheryl Acetate (Vitamin E)</p>	Active Ingredient	Purpose	Ethyl Alcohol 70% w/v.....	Antiseptic	<p style="text-align: center;">Safe Choice</p> <p style="text-align: center;">TRADEMARK BRAND</p> <p style="text-align: center;"><i>Zestfully Efficacious</i></p> <p style="text-align: center;">HAND SANITIZER</p> <p style="text-align: center;">KILLS 99.9% OF GERMS*</p> <p style="text-align: center;">Antibacterial</p> <p style="text-align: center;">70% ALCOHOL</p> <p style="text-align: center;">2 FL OZ (59 ML)</p>	<p style="text-align: center;">KILLS 99.9%*</p> <p style="text-align: center;">OF GERMS</p> <p style="text-align: center;">ANTIBACTERIAL</p> <p style="text-align: center;"><i>Added</i> VITAMIN E</p> <p style="text-align: center;">70% ALCOHOL</p> <p style="text-align: center;">NON-STERILE SOLUTION</p> <p style="text-align: center;">SAFE, EFFECTIVE & Zestful!</p> <p style="text-align: center;">FOR MORE EFFICACIOUS PRODUCTS, GO TO TRADEMARKBRAND.COM</p> <p style="text-align: center;">TRADEMARK BRAND</p>
Active Ingredient	Purpose					
Ethyl Alcohol 70% w/v.....	Antiseptic					
<p style="text-align: right;">*Kills 99.99% of many common germs that may cause illness</p> <div style="display: flex; align-items: center;">  <div style="text-align: center;"> <p>TRADEMARK BRAND</p> <p>DISTRIBUTED BY TRADEMARK BRAND LLC 1 Bridge Plaza N Ste 475 Fort Lee, NJ 07024 Made in Mexico</p> </div> </div>						

Package Label - TRADEMARK

250 ml NDC:79337-172-02

250 ml NDC: 79337-172-02

Drug Facts	70% ALCOHOL	Added VITAMIN E
Active Ingredient	TRADEMARK BRAND	70% ALCOHOL
Ethyl Alcohol 70% v/v.....	<i>Zestfully Efficacious</i>	KILLS 99.9% OF GERMS*
Purpose	HAND SANITIZER	— Non-Sterile Solution —
Use(s)	KILLS 99.9% OF GERMS*	TRADEMARK BRAND
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	8.4 OZ (250 ML)	DISTRIBUTED BY TRADEMARK BRAND LLC 1 Bridge Plaza N Ste 475 Fort Lee, NJ 07024
Warnings		Made in Mexico
For external use only. Flammable. Keep away from heat or flame.		FOR MORE EFFICACIOUS PRODUCTS, GO TO TRADEMARKBRAND.COM
Do not use		
<ul style="list-style-type: none"> ■ 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.		
Directions		
<ul style="list-style-type: none"> ■ 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		
<ul style="list-style-type: none"> • Store in between 5°- 30°C (41°- 86°F) • Avoid freezing and excessive heat above 40°C (104°F) 		
Inactive Ingredients Water (Aqua), Carbomer, Glycerin, Triethanolamine, Tocopheryl Acetate (Vitamin E)		
*Kills 99.99% of many common germs that may cause illness		

Package Label - TRADEMARK

1000 ml NDC:79337-172-03

|1000 ml NDC: 79337-172-03

Safe Choice

Drug Facts

Active Ingredient Ethyl Alcohol 70% v/v
Purpose Antiseptic

Use(s)
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
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Inactive Ingredients
Water (Aqua), Carbomer, Glycerin, Triethanolamine, Tocopheryl Acetate (Vitamin E)

*Kills 99.99% of many common germs that may cause illness



Made in Mexico

70% ALCOHOL

TRADEMARK BRAND

Zestfully Efficacious

HAND SANITIZER

KILLS 99.9% OF GERMS*

NON-STERILE SOLUTION

Added VITAMIN E

70% ALCOHOL

SAFE & Effective

33.8 OZ (1 L)



DISTRIBUTED BY
TRADEMARK BRAND LLC
1 Bridge Plaza N Ste 475
Fort Lee, NJ 07024

FOR MORE EFFICACIOUS PRODUCTS, GO TO
TRADEMARKBRAND.COM

Package Label - TRADEMARK

3785 ml NDC: 79337-172-04

| 3785 ml NDC: 79337-172-04

Safe Choice

TRADEMARK BRAND

Zestfully Efficacious

KILLS 99.9% OF GERMS | **HAND SANITIZER** | **70% ALCOHOL**

Added VITAMIN E

128 OZ (3.7 L)



DISTRIBUTED BY
TRADEMARK BRAND LLC
1 Bridge Plaza N Ste 475
Fort Lee, NJ 07024

Made in Mexico

FOR MORE EFFICACIOUS PRODUCTS, GO TO
TRADEMARKBRAND.COM

SAFE & EFFECTIVE

Non-Sterile Solution



Drug Facts

Active Ingredient Ethyl Alcohol 70% v/v.....	Purpose Antiseptic
Use(s) Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
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*Kills 99.99% of many common germs that may cause illness

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: 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
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.15 mL in 100 mL

Packaging

#	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	
2	NDC:79337-172-	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/19/2020	

2	02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/19/2020	
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.