

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.

PLUS DE SANTE 60 ML ORGANIKISIMO

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, Polyacrylic, glycerin, Triethanoamine

Package Label - Principal Display Panel



HAND SANITIZER

with Moisturizers

70% Alcohol

2.02 FL OZ (60ML)

Drug Facts

| Active ingredient | Purpose |
|------------------------|------------|
| Ethyl Alcohol, 70% v/v | Antiseptic |

| Use[s] |
|---|
| <ul style="list-style-type: none"> 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 |
|---|
| <ul style="list-style-type: none"> In children less than 2 months of age On open skin wounds. |

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| Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. |
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| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. |
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| Directions |
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| <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 between 15-30 °C (59-86 °F) Avoid freezing and excessive heat above 40 °C (104 °F) |

| Inactive ingredients |
|---|
| Water, Polyacrylic acid, Glycerin, Triethanolamine. |

| |
|---|
| Questions or comments? +52 1 81 8685 5372 ■ feedback@grupodyasa.com |
|---|



Manufactured by:
Organikísimo, S.A. de C.V.,
Av. Industria Siderúrgica
#100, Parque Industrial
Pesquería, Pesquería,
Nuevo León, México.
66650.
Lot number and expiration
date on container



PRODUCT OF MEXICO

60 ml NDC:79337-124-01

HAND SANITIZER

ethyl alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79337-124 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M) | 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) | 28.5 mL in 100 mL |
| POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F) | 0.6 mL in 100 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
| | | | | |

| | | | | |
|---|------------------|--|------------|--|
| 1 | NDC:79337-124-01 | 60 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(79337-124) |

Revised: 7/2020

Organikisimo, S.A. de C.V.