

HAND SANITIZER- ethyl alcohol cloth
ORGANIKISIMO SA DE CV

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.

HAND SANITIZER WIPES BAG

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer wipes

Use

Hand Sanitizer wipes 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

- . Rub hands together until dry. dispose properly.
- Supervise children under 6 years of age when using this product.

Other information

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

Inactive ingredients

water,Glycerin, Polyethylene glycol, Isopropyl myristate

Package Label - Principal Display Panel

210 ML NDC 79337-157-01

Convenient at: Home,
Restaurants, Public Spaces,
Office, Gyms, Healthcare, etc.

PLUS DE SANTÉ

HAND SANITIZING WIPES

**Kill
Bacteria**

**Soft sensation
on hands**

**70%
ALCOHOL**

100 WIPES

<p>Drug Facts</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Active ingredient</td> <td style="width: 50%;">Purpose</td> </tr> <tr> <td>Ethyl Alcohol, 70% v/v</td> <td>Antiseptic</td> </tr> <tr> <td colspan="2">Use[s]</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> ■ Hand Sanitizer Wipes to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. </td> </tr> <tr> <td colspan="2">Warnings</td> </tr> <tr> <td colspan="2">For external use only. Flammable. Keep away from heat or flame.</td> </tr> <tr> <td colspan="2">Do not use</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> ■ In children less than 2 months of age. ■ On open skin wounds. </td> </tr> <tr> <td colspan="2">When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</td> </tr> <tr> <td colspan="2">Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</td> </tr> <tr> <td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> </table>	Active ingredient	Purpose	Ethyl Alcohol, 70% v/v	Antiseptic	Use[s]		<ul style="list-style-type: none"> ■ Hand Sanitizer Wipes 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. 		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.		<p>Drug facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> ■ Rub your hands with a wipe until dry, dispose properly. ■ Supervise children under 6 years of age when using this product. <p>Other information</p> <ul style="list-style-type: none"> ■ Store between 15-30 °C (59-86 °F) ■ Avoid freezing and excessive heat above 40 °C (104 °F) <p>Inactive ingredients Water, Glycerin, Polyethylene glycol, Isopropyl myristate.</p> <p>Questions or comments? +52 1 81 8685 5372 ■ feedback@grupodyasa.com</p> <p style="font-size: 0.8em;">Manufactured by: Organikisimo, S.A. de C.V., Av. Industria Siderúrgica #100, Parque Industrial Pesquería, Pesquería, Nuevo León, México. 66650. Lot number and expiration date on container</p> <p style="text-align: right;">PRODUCT OF MEXICO </p>
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HAND SANITIZER

ethyl alcohol cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79337-157
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
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	0.37 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.68 mL in 100 mL
WATER (UNII: 059QF0KO0R)	28.46 mL in 100 mL
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	0.49 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79337-157-01	210 mL in 1 BAG; Type 0: Not a Combination Product	07/27/2020	

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 SA DE CV (951579669)

Registrant - ORGANIKISIMO SA DE CV (951579669)

Establishment

Name	Address	ID/FEI	Business Operations
ORGANIKISIMO SA DE CV		951579669	manufacture(79337-157)

Revised: 7/2020

ORGANIKISIMO SA DE CV