

KINE HEARTS WIPES- ethyl alcohol wipes swab
Finca Montes LLC

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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydroethylcellulose(1% v/v)
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Wipe 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

- 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

purified water USP

70Label

100 Wipes NDC 77421-007-001

<p>Drug Facts</p> <table border="1"> <tr> <td>Active ingredients Isopropyl Alcohol 70%</td> <td>Purpose First aid antiseptic</td> </tr> <tr> <td colspan="2">Use • First aid to help prevent the risk of infection in: • minor cuts • scrapes • burns</td> </tr> <tr> <td colspan="2">Warnings • For external use only</td> </tr> <tr> <td colspan="2">Flammable • Keep away from fire or flame, heat, sparks, electrical</td> </tr> <tr> <td colspan="2">Ask a doctor before use if you have deep or puncture wounds, animal bites or serious burns</td> </tr> <tr> <td colspan="2">Do not use • In eyes or apply over large areas of the body • longer than 1 week unless directed by a doctor</td> </tr> <tr> <td colspan="2">Stop use and ask a doctor if • condition persists or gets worse</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 at (1-800-222-1222). Do not get in eyes.</td> </tr> <tr> <td colspan="2">Directions • Clean the affected area • apply product on the affected area 1 to 3 times a day • may be covered with a sterile bandage • if bandaged, let dry first</td> </tr> <tr> <td colspan="2">Other information Do not apply internally. Keep container tightly closed and at controlled room temperature 15°–30°C (59°–86°F). Hold away from face when opening.</td> </tr> <tr> <td colspan="2">Inactive ingredients purified water</td> </tr> </table> <p>Información del Medicamento Ingredientes activos: Alcohol isopropílico 70%. Propósito: Antiséptico de primeros auxilios. Utilice los primeros auxilios para evitar el riesgo de infecciones en cortes leves, raspones y quemaduras. Advertencia: Únicamente para uso externo. Irritante. Mantenga el producto alejado del fuego, las llamas, el calor, las chispas y los objetos eléctricos. Consulte a un médico antes de usarlo si tiene heridas profundas o de punción, mordeduras de animales o quemaduras graves. No lo use en los ojos ni lo aplique en superficies grandes del cuerpo. No lo use más de 1 semana, salvo que lo indique un médico. Suspense el uso y consulte a un médico si la condición persiste o empeora. Mantenga fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o comuníquese de inmediato con un centro de intoxicaciones llamando al (1-800-222-1222). No lo coloque en los ojos. Instrucciones: Limpie la zona afectada, aplique el producto en la zona afectada de 1 a 3 veces al día. Si vez cubrió con una venda estéril. Si aplica un vendaje, deje secar la herida antes. Otra información: No aplique internamente. Mantenga la lata bien cerrada y a temperatura ambiente controlada 15°–30 °C (59°–86 °F). Alejado de la cara para abrir. Ingredientes inactivos: Agua purificada.</p>	Active ingredients Isopropyl Alcohol 70%	Purpose First aid antiseptic	Use • First aid to help prevent the risk of infection in: • minor cuts • scrapes • burns		Warnings • For external use only		Flammable • Keep away from fire or flame, heat, sparks, electrical		Ask a doctor before use if you have deep or puncture wounds, animal bites or serious burns		Do not use • In eyes or apply over large areas of the body • longer than 1 week unless directed by a doctor		Stop use and ask a doctor if • condition persists or gets worse		Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at (1-800-222-1222). Do not get in eyes.		Directions • Clean the affected area • apply product on the affected area 1 to 3 times a day • may be covered with a sterile bandage • if bandaged, let dry first		Other information Do not apply internally. Keep container tightly closed and at controlled room temperature 15°–30°C (59°–86°F). Hold away from face when opening.		Inactive ingredients purified water		 <p>70%</p> <p>ALCOHOL WIPES</p> <p>Toallitas húmedas con 70% de alcohol isopropílico</p> <p>First Aid Antiseptic Antiséptico de primeros auxilios</p> <p>For Treatment of Minor Cuts and Scrapes</p> <p>100 WIPES 7.0" x 5.25" (17.8 cm x 14.6 cm)</p> <p>CAUTION KEEP OUT OF REACH OF CHILDREN See back panel for additional cautionary statements.</p> <p>CUIDADO MANTÉNGA FUERA DEL ALCANCE DE LOS NIÑOS See back panel for additional cautionary statements.</p> <p>MADE IN USA Distributed by: Kmart Corporation Hoffman Estates, IL 60179 Shop.kmart.com</p> <p>SATISFACTION GUARANTEE Thank you for purchasing this quality product. If you are unsatisfied for any reason, return the unused portion to the store for a full refund or call 1-800-642-7885.</p> <p>PLEASE RECYCLE</p>
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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77421-007
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	
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77421-007-01	300 mL in 1 POUCH; Type 0: Not a Combination Product	05/04/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/04/2020		

Labeler - Finca Montes LLC (117514295)

Establishment			
Name	Address	ID/FEI	Business Operations
Finca Montes LLC		117514295	manufacture(77421-007)

Revised: 6/2020

Finca Montes LLC