

HAND SANITIZER- ethanol gel
BOTANICALS INTERNACIONAL 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.

INATEK 70% ALCOHOL BASED HAND SANITIZER

Active Ingredient

Ethyl Alcohol 70% v/v

Keep out of reach of children

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

Purpose

Antiseptic

Warnings

Warnings

- Flammable. Keep away from fire or flame.
- For external use only.

Directions

Direction:

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years old should be supervised when using this product.

Uses

Use: hands sanitizer to help decrease bacteria on the skin

Stop use and ask a doctor

Stop use and ask a doctor if irritation or rash appears and lasts.

When using this product

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Inactive ingredients

Inactive ingredients:

water 28%, glycerin 1%, carbopol 940 0.50%,TEA 85 0.50%,

Other information

Store below 110 °F (43 °C)

May discolor certain fabrics

Principal Display Panel

NDC: 51384-002-01



Drug Facts

Active ingredients.....Purpose
Ethyl Alcohol 70%.....Antiseptic

Use: hands sanitizer to help decrease bacteria on the skin.

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Direction: Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years old should be supervised when using this product.

Other information. Store below 110°F (43°C)
May discolor certain fabrics or surfaces.

Inactive ingredients: water 28%, glycerin 1%, carbopol 940 0.50%, TEA 85 0.50%,



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MADE IN MEXICO

Manufacture by; Botanicals Internacional S.A. de C.V. Av. De la luz 73-B
Parque Industrial la Luz, Cuautitlán Izcalli, México, México, C.P. 54716
Imported by: INAMBTEC S.A. DE C.V Tel: (52) 722 - 492 - 8880.

HAND SANITIZER

ethanol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:51384-002

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: 059QF0KO0R)		28 mL in 100 mL		
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)		0.5 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)		1 mL in 100 mL		
TROLAMINE (UNII: 9O3K93S3TK)		0.5 mL in 100 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51384-002-01	900 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/13/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/13/2020		

Labeler - BOTANICALS INTERNACIONAL S.A. DE C.V (823968961)

Registrant - BOTANICALS INTERNACIONAL S.A. DE C.V. (823968961)

Establishment

Name	Address	ID/FEI	Business Operations
BOTANICALS INTERNACIONAL S.A. DE C.V.		823968961	manufacture(51384-002)

Revised: 6/2020

BOTANICALS INTERNACIONAL S.A. DE C.V