

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



## Drug Facts

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Ethyl Alcohol 70%.....Antiseptic

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

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### Warnings

**Flammable.** Keep away from fire or flame.



**For external use only.**

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

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

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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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**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.

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

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**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.

900ML NDC: 51384-002-01

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

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**FRONT DISPLAY**





900ML NDC: 51384-002-01

## HAND SANITIZER

ethanol gel

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:51384-002 |
| <b>Route of Administration</b> | 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: 5/2020

BOTANICALS INTERNACIONAL S.A. DE C.V