

## **HAND SANITIZER- ethyl alcohol gel**

### **Vi-Jon**

*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.*

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### **Germ-x 989**

#### **Active ingredient**

Ethyl alcohol 62%

#### **Purpose**

Antiseptic

#### **Uses**

- to decrease bacteria on the skin that could cause disease
- recommended for repeated use

#### **Warnings**

For external use only: hands

#### **Flammable**

Keep away from heat and flame

#### **when using this product**

- keep out of eyes. In case of contact with eyes, flush thoroughly with water
- avoid contact with broken skin
- do not inhale or ingest

#### **Stop use and ask a doctor**

- if irritation and redness develops
- condition persists for more than 72 hours

#### **Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away

#### **Directions**

- wet hands thoroughly with product and allow to dry without wiping
- for children under 6, use only under adult supervision
- not recommended for infants

#### **Other information**

- do not store above 105°F

- may discolor some fabrics
- harmful to wood finishes and plastics

### Inactive ingredients

water, glycerin, tocopheryl acetate, retinyl palmitate, carbomer, fragrance, benzophenone-4, mannitol, cellulose, hydroxypropyl methylcellulose, ultramarines, blue 1, red 40, yellow 5

### claims

Effective at eliminating 99.99% of many common harmful germs and bacteria in as little as 15 seconds.

### adverse reactions section

Distributed by: Vi-Jon 8515 Page Ave.  
St. Louis, MO 63114

### principal display panel

germ-x

hand sanitizer

coconut water

KILLS 99.99% OF GERMS

1.11 FL OZ (32 mL)



**HAND SANITIZER**

ethyl alcohol gel

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:11344-989 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| <b>Ingredient Name</b>                                 | <b>Basis of Strength</b> | <b>Strength</b> |
|--|--------------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL                  | 545 mg in 1 mL  |

### Inactive Ingredients

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| WATER (UNII: 059QF0KO0R)  |                 |
| GLYCERIN (UNII: PDC6A3C0OX)   |                 |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                               |                 |
| VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)                                      |                 |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) |                 |
| SULISOBENZONE (UNII: 1W6L629B4K)  |                 |
| MANNITOL (UNII: 3OWL53L36A)   |                 |
| CELLULOSE ACETATE (UNII: 3J2P07GVB6)  |                 |
| HYPROMELLOSES (UNII: 3NXW29V3WO)  |                 |
| ULTRAMARINE BLUE (UNII: B9WR998BI)  |                 |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)  |                 |
| FD&C RED NO. 40 (UNII: WZB9127XOA)  |                 |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)  |                 |

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:11344-989-06 | 32 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package | 10/08/2014           |                    |

### Marketing Information

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final   | part333A  | 10/08/2014                  |                           |

**Labeler** - Vi-Jon (150931459)

**Registrant** - Vi-Jon (790752542)

**Establishment**

| Name   | Address | ID/FEI    | Business Operations    |
|--------|---------|-----------|------------------------|
| Vi-Jon |         | 088520668 | manufacture(11344-989) |

Revised: 1/2020

Vi-Jon