

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.

Germ-X 980

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, ultamarines, ext.violet 2, red 33

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
wild berry
KILLS 99.99% OF GERMS
1.11 FL OZ (32 mL)



HAND SANITIZER			
ethyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11344-980

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	545 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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)	
EXT. D&C VIOLET NO. 2 (UNII: G5UX3K0728)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11344-980-06	32 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/08/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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(11344-980)