

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 Hand Sanitizer

053

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 or 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

aloe barbadensis gel, carbomer, FD&C blue no.1, FD&C yellow no.5, fragrance, glycerin, isopropyl alcohol, isopropyl myristate, propylene glycol, tocopheryl acetate, water

Questions

1-866 MY GERM-X - 1-866-694-3769

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

www.germx.com

053.002/053AE/AF

principal display panel

germ-X

HAND SANITIZER

KILLS 99.99% OF GERMS

MOISTURIZING WITH ALOE

3 fl oz (88 mL)



HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11344-053
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
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ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11344-053-16	59 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/05/2009	
2	NDC:11344-053-34	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/05/2009	
3	NDC:11344-053-42	828 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/05/2009	
4	NDC:11344-053-21	89 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/05/2009	
5	NDC:11344-053-38	295 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/05/2009	
6	NDC:11344-053-32	355 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/05/2009	
7	NDC:11344-053-06	887 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/05/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/05/2009	

Labeler - Vi-Jon (150931459)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		088520668	manufacture(11344-053)