

ANTIBACTERIAL HAND SANITIZER- alcohol gel PERMATEX

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.

Advanced Hand Sanitizer 370.001/370AE rev 1

Active Ingredient

Ethyl alcohol 70%

purpose

Antiseptic

Use

- 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

water, glyceryl caprylate/caprata, glycerin, isopropyl myristate, tocopheryl acetate, acrylates/C10-30 alkyl acrylate crosspolymer, fragrance, benzophenone-4

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

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Solon, OH 44139/ Assembled in U.S.A. with U.S. and global materials

www.permatex.com

Principal display panel

Fast Orange

Moisturizing Formula

Advanced Hand Sanitizer

Kills more than 99.99% of germs

Moisturizing formula with Vitamin E

8 FL OZ (236 mL)



ANTIBACTERIAL HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70616-370
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
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water (UNII: 059QF0K00R)	
GLYCERYL CAPRYLATE/CAPRATE (UNII: G7515SW10N)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
SULISOBENZONE (UNII: 1W6L629B4K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70616-370-16	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/02/2015	
2	NDC:70616-370-34	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/02/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/02/2015	

Labeler - PERMATEX (964477025)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(70616-370)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(70616-370)