

VIVITAR ETHYL ALCOHOL ANTISEPTIC HAND SANITIZER- ethyl alcohol gel
Taizhou Duorui Biotechnology Co., Ltd.

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.

Ethyl Alcohol Antiseptic Hand Sanitizer Gel

Drug Facts

Active ingredient

Ethyl alcohol 75% v/v

Purpose

Antiseptic

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame
For external use only

Do not use

- in children less than 12 months of age
- on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- 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
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

store below 110°F (43°C)

Inactive ingredients

aloe extract, alpha tocopherol, carbomer, fragrance (parfum), glycerin, triethanolamine, water

Questions? +1-800-592-9541

You may also report serious side effects to this phone number.

We are available 24x7

Distributed by

Sakar International
195 Carter Drive,
Edison, NJ 08817
www.vivitar.com

Made in China

VIVITAR®

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Keep All Relevant Information for Future Reference.

Packaging



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195 Carter Drive,
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Made in China
Lot no.: 6530021
Expiry Date: 04/15/2023
Mfg Date: 04/15/2021

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DRUG FACTS TABLE

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Expiry Date: Factory to Enter
Mfg Date: Factory to Enter

Item# xxxxxx DPCI#xxxxxxx

MID xxxxxxxx

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VIVITAR ETHYL ALCOHOL ANTISEPTIC HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80800-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE (UNII: V5VD430YW9)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80800-004-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/14/2021	

Labeler - Taizhou Duorui Biotechnology Co., Ltd. (713362289)

Establishment

Name	Address	ID/FEI	Business Operations
Taizhou Duorui Biotechnology Co., Ltd.		713362289	manufacture(80800-004)

Revised: 4/2021

Taizhou Duorui Biotechnology Co., Ltd.