

VIVITAR ETHYL ALCOHOL ANTISEPTIC HAND SANITIZER- ethyl alcohol gel
Sakar International, Inc.

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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Sakar International
195 Carter Drive,
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Lot no.: 6530021
Expiry Date: 04/15/2023
Mfg Date: 04/15/2021

Item# 10-1741-03 DPCI#24-04-110

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Drug Facts (continued)

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Expiry Date: 04/15/2023
Mfg Date: 04/15/2021

Item# 10-1741-LV DPCI#24-04-289

Keep All Relevant Information for Future Reference.

Drug Facts (continued)

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Drug Facts (continued)

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Expiry Date: 04/15/2023
Mfg Date: 04/15/2021

Item# 10-1741-0L DPCI#24-04-095

Keep All Relevant Information for Future Reference.

DRUG FACTS TABLE

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Made in China
Lot no.: Factory to Enter(MID#)
Expiry Date: Factory to Enter
Mfg Date: Factory to Enter

Item# xxxxxx DPCI#xxxxxx

MID xxxxxxx

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VIVITAR ETHYL ALCOHOL ANTISEPTIC HAND SANITIZER

ethyl alcohol gel

| Product Information | | | |
|--|----------------|--------------------|-----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79821-008 |
| Route of Administration | TOPICAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingrdient 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:79821-008-01 | 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 - Sakar International, Inc. (086413028)

Revised: 3/2021

Sakar International, Inc.