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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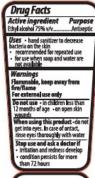
Keep All Relevant Information for Future Reference.

Packaging









Drug Facts (continued) Warnings

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Drug Facts (continued) Warnings

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DRUG FACTS TABLE



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Distributed by Sakar International 195 Carter Drive, Edison, NJ 08817

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

Item# xxxxxx DPCI#xxxxxxx

VIVITAR

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VIVITAR ETHYL ALCOHOL ANTISEPTIC HAND SANITIZER

ethyl alcohol gel

Product Information

HUMAN OTC DRUG NDC:79821-008 **Product Type** Item Code (Source)

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				
Strength				

l	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		NDC:79821-008- 01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2021		

Marketing In	larketing 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.