#### ALH HAND SANITIZER GEN- alcohol gel Advanced Local Health LLC

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.

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#### ALH Hand Sanitizer Gen

Drug Facts

# **Active Ingredient**

Ethyl Alcohol 70% v/v

# Purpose

Antiseptic

# Uses

To decrease bacteria on the skin when water, soap & towel are not available – Recommended for repeated use.

# Warnings

#### For external use only.

# Flammable

Keep away from fire or flame.

*When using this product* keep out of eyes. In case of contact with eyes, rinse thoroughly with water. Do not use on broken or irritated skin.

*Stop use and ask a doctor if* irritation or redness develop and last more than 72 hours.

# Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

# Directions

Apply enough product to wet hands. Rub hands together until dry. Supervise children in use of this product.

# Other information

- Do not store above 105 °F (40 °C).
- May discolor certain wood surfaces.

# **Inactive Ingredients**

Water (Aqua) (EAU), Glycerin, Carbomer, Propylene Glycol, Phenoxyethanol / Iodopropynyl Butylcarbamate, Aloe Vera extract (*Aloe barbadensis*), Aminomethyl Propanol, Ext. Violet 2 (CI 60730), Tetrasodium EDTA.

Distributed by: Advanced Local Health LLC, Doral, Florida, 33166

# PRINCIPAL DISPLAY PANEL - 415 ml Bottle Label

HAND SANITIZER CONTAINS 70% ETHYL ALCOHOL TOPICAL SOLUTION WITH ALOE VERA 14 Fl. Oz. (415 ml) 415ADVA03F



ALH HAND SANITIZER GEN				
alcohol gel				
Product Information				
Product Type	HUMAN OTC DRUG	Ite m Coo	de (Source)	NDC:74264-003
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

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
EXT. D&C VIOLET NO. 2 (UNII: G5UX3K0728)	
EDETATE SODIUM (UNII: MP1J8420LU)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	

#### Packaging

Package Description	Marketing Start Date	Marketing End Date
200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2020	
415 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2020	
	200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product 415 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	Package DescriptionDate200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product08/04/2020415 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination 08/04/202008/04/2020

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333A	08/04/2020	

# Labeler - Advanced Local Health LLC (117466501)

Establishment			
Name	Address	ID/FEI	Business Operations
TECNOGLOBAL PH7		813006665	MANUFACTURE(74264-003)

Revised: 8/2020

Advanced Local Health LLC